

**THE DEVELOPMENT OF A COMPREHENSIVE FIDELITY MONITORING  
PLAN FOR A WEB-BASED PSYCHO-EDUCATIONAL INTERVENTION: THE  
WRITE SYMPTOMS STUDY**

by

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The purpose of this study was to develop and evaluate a comprehensive intervention fidelity monitoring plan for a web-based symptom management intervention for women with recurrent ovarian cancer, the nurse-delivered WRITE Symptoms intervention. Because the intervention was designed to be flexible and dynamic to meet the individual needs of each participant, a comprehensive monitoring plan was necessary to ensure internal validity of the trial evaluating the efficacy of WRITE Symptoms. The first phase of this study was the development of a fidelity instrument. The instrument development began with a review of fidelity literature and the underlying intervention theory to guide item selection and scaling. An iterative process was used to identify, develop, and refine the items for the instrument and the interventionist manual. Several rounds of expert review and item revision resulted in a preliminary instrument to be used in the initial evaluation process. A sample of five mock intervention sessions was used to evaluate inter-rater reliability for the instrument. Modifications were made to items with low reliability. The revised instrument contained 13 subscales with 54 items. The revised instrument was then evaluated using twenty completed interventions from the WRITE Symptoms RCT. Analyses included inter-rater reliability and two week intra-rater reliability. The instrument demonstrated acceptable psychometric properties. Inter-rater reliability based on weighted Kappa range from 0.47 to 1.00 and percentage of agreement (POA) range from 85 to 100 for each

individual item. Intra-rater reliability was also good with weighted Kappa of 0.48 to 1.00 and POA of 85 to 100 for each individual item. An intervention fidelity-manual was developed to address two topics: (1) how to use the instrument to monitor fidelity of the nurse-delivered WRITE Symptoms intervention and (2) how to train raters to use the instrument. Finally, an analytic plan was proposed for understanding the influence of fidelity on intervention outcomes. Further research should address two questions: (1) is intervention fidelity a predictor of intervention outcomes and (2) what is the active ingredient of the nurse-delivered WRITE Symptoms intervention?

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## **1.0 INTRODUCTION**

### **1.1 SPECIFIC AIMS**

Intervention fidelity refers to the degree to which a treatment or intervention is administered as intended. Intervention fidelity is concerned with the accuracy and reliability of delivery of an intervention. Therefore, assessing intervention fidelity is essential to evaluating the internal validity of a clinical trial and to making inferences regarding the efficacy of an intervention. The Written Representational Intervention to Ease Symptoms (WRITE Symptoms) is a web-based symptom management intervention for women with recurrent ovarian cancer based on the Representational Approach (RA) to patient education (Donovan & Ward, 2001; Donovan et al., 2007). The RA is an intervention theory derived from theory regarding cognition of illness (Kleinman, Eisenberg, & Good, 1978; Leventhal et al., 1997) and theory regarding how conceptual change occurs (Hewson & Thorley, 1989; Posner, Strike, Hewson, & Gertzog, 1982). The nurse-delivered WRITE Symptoms intervention has been designed to be flexible and dynamic to meet the individual needs of each participant. While individualization is important for increasing the relevance of the information to each participant, it may increase the likelihood of unsystematic variation in intervention delivery which can result in invalid conclusions about the effect of the intervention on study outcomes. Since the goal of the WRITE Symptoms study is to determine if changes in symptom-related outcomes are the result of a systematic

manipulation of the independent variable and not due to random factors, it is important to demonstrate that the nurse-delivered WRITE Symptoms intervention is implemented as intended and is not altered or changed substantially by interventionists responsible for the delivery of the intervention.

The purpose of this study was to develop and evaluate a comprehensive intervention fidelity monitoring plan for the trial evaluating the efficacy of WRITE Symptoms. Our expectation is that the fidelity plan will provide guidelines for implementing and evaluating fidelity in the WRITE Symptoms study, and advance the science of intervention delivery in three important ways by: (1) providing a detailed exemplar on methods for designing and evaluating a fidelity instrument that links a specific intervention to its underlying intervention theory; (2) identifying essential components for all interventions based on the Representational Approach; and (3) identifying essential components for delivering web-based psycho-educational interventions. Although many intervention fidelity instruments have been developed for a range of clinical trials, they are focused on monitoring either face-to-face counseling or telephone interventions. None of them specifically address web-based psycho-educational interventions or RA-based interventions.

The purposes of this study are to (1) develop and refine the WRITE Symptoms fidelity instrument, (2) evaluate the reliability of the WRITE Symptoms fidelity instrument, (3) establish a fidelity monitoring plan for a large multisite randomized clinical trial (RCT) of the WRITE Symptoms intervention, and (4) develop an analytic plan to understand the influence of fidelity on the intervention outcomes. Research questions to be addressed by this study are:

1. What are the essential specific and non-specific intervention components to be included in the WRITE Symptoms fidelity instrument?

2. Is the WRITE Symptoms fidelity instrument a reliable measure of intervention fidelity as evidenced by: (1) inter-rater reliability and (2) intra-rater reliability (test re-test reliability)?
3. What is the fidelity monitoring plan for the WRITE Symptoms intervention?
4. What is the analytic plan to understanding the influence of fidelity on the intervention outcomes:
  - a. Is intervention fidelity a predictor of intervention outcomes (symptom severity, symptom consequences, and symptom distress)?
  - b. What are the active ingredients of the nurse-delivered WRITE Symptoms intervention?

## **1.2 BACKGROUND AND SIGNIFICANCE**

### **1.2.1 Intervention fidelity**

One of the most important aspects of a behavioral intervention study is the demonstration that changes in the dependent variables are caused by systematic changes in the independent variable, rather than by changes in extraneous variables (Gresham, Gansle, & Noell, 1993; Peterson, Homer, & Wonderlich, 1982; Sidman, 1960; Stein, Sargent, & Rafaels, 2007). Therefore, clear and specific descriptions of the independent and dependent variables are required for drawing accurate conclusions regarding the relationships between the two variables. A great deal of time and resources have been dedicated to generating operational definitions and developing and testing the reliability and validity of constructs to be used as dependent variables and covariates in intervention studies. Unfortunately, comparable attention has rarely been given to operationalizing and measuring the actual intervention (the independent variable) (Gresham et al., 1993; Peterson et al., 1982). It is increasingly recognized, however, that if data to support the accurate operationalization and delivery of the independent variable are not reported, conclusions of a study are not defensible. To merely assume that the intervention was applied or delivered as outlined in a method section or intervention manual is inadequate (Gresham et al., 1993). Therefore, it is essential that independent variables be clearly defined, and their delivery be evaluated in intervention studies.

The degree to which an independent variable is delivered as intended has come to be known as intervention fidelity (also recognized as treatment fidelity or treatment integrity)



(Carroll et al., 2000; Gresham et al., 1993; Peterson et al., 1982; Santacrose, Maccarelli, & Grey, 2004). The concept of intervention fidelity has been recognized since the late 1960s (Bond, Evans, Salyers, Williams, & Kim, 2000; Moncher & Prinz, 1991; Waltz, Addis, Koerner, & Jacobson, 1993 ). Originally, the concept of intervention fidelity arose from drug trials (Carroll et al., 2000; Santacrose et al., 2004; Song, Happ, & Sandelowski, 2010). At the most basic level, fidelity addresses the question of whether or not a treatment or intervention was accurately and reliably delivered as intended.

The need to attend to intervention fidelity in the design and conduct of RCTs is of great importance. The Consolidated Standards of Reporting Trials (CONSORT) emphasize its importance by including documentation of fidelity to intervention delivery as a quality component of RCTs (Altman et al., 2001). According to recommendations from the Behavior Change Consortium, assessment of fidelity should be a standard requirement for a research study (Bellg et al., 2004). Multiple scholars point out that assurance of intervention fidelity allows for more accurate interpretation of study findings (Bellg et al., 2004; Borrelli et al., 2005; Carroll et al., 2007; Santacrose et al., 2004). Careful attention to operationalizing key elements of an intervention into a comprehensive intervention fidelity plan is the means to ensure that the intervention is implemented as intended and that the intervention is accurately tested (Resnick, Bellg et al., 2005) because it minimizes the risk for variation in intervention delivery (Horner, Rew, & Torres, 2006), (Resnick, Bellg et al., 2005). Through this process, construct validity (the extent to which the operationalization of a variable is consistent with its underlying theoretical construct) is a by-product accomplished partly by ensuring correspondence between the theory of the study and its protocol (Moncher & Prinz, 1991). Conversely, when there is no formal assessment of treatment fidelity in intervention studies, it may not be clear that the intervention

was operationalized as intended or delivered as intended. Accordingly, it is impossible to accurately determine a causal link between the specific intervention and outcomes, that is, internal validity is not guaranteed. This dilemma can increase: (1) type I error, in which the researcher declares a significant treatment effect that does not actually exist, leading to acceptance of ineffective interventions that appear effective because other elements were unintentionally added during the delivery of the interventions; and (2) type II error, in which the researcher declares the intervention ineffective because it was implemented poorly, leading to abandonment of potentially effective interventions (Bellg et al., 2004; Borrelli et al., 2005; Carroll et al., 2007; Ellis, Naar-King, Templin, Frey, & Cunningham, 2007; Horner et al., 2006; Moncher & Prinz, 1991; Santacrose et al., 2004).

Attention to intervention fidelity also enhances external validity since an intervention that can be delivered with high levels of fidelity has the potential to be consistently reproducible across research samples and settings. This is important to the effective translation and dissemination of behavioral change strategies from research settings to real-world clinical settings (Bellg et al., 2004). Assuring optimal intervention fidelity may also decrease the costs of a study. Since statistical power increases as unintended variability of the independent variable decreases, target effect sizes may be identified with a smaller sample (Resnick, Inguito et al., 2005). Moreover, the information obtained throughout the course of the study regarding intervention fidelity is critical for helping the researcher to explain findings and to adjust the delivery of the intervention as appropriate (Resnick, Inguito et al., 2005).

Despite growing recognition of the importance of intervention fidelity, only 5-20% of studies reported that fidelity was addressed when conducting the studies (Borrelli et al., 2005; Gresham, Gansle, & Noell, 1993; Moncher & Prinz, 1991; Peterson et al., 1982; Tucker &

Blythe, 2008). Peterson and colleagues (1982) discovered that only 20% of 539 studies published from 1968 to 1980 in the Journal of Applied Behavior Analysis (JABA) measured intervention fidelity. Gresheam, Gansle, and Noell (1993) reviewed all applied behavior analysis studies with children as subjects published in the JABA between 1980 and 1990 and found that only approximately 16% of these studies measured fidelity. Fewer than six percent of 359 studies reviewed by Moncher and Prinz used a manual, supervision, and adherence check to ensure fidelity (Moncher & Prinz, 1991). Borrelli and colleagues evaluated whether 371 articles published in 1999 and 2000 reported implementing each of three important treatment fidelity strategies: (1) maintaining provider skills, (2) checking adherence to protocol, and (3) using a treatment manual. The authors discovered that only 12 % of the articles reported using all 3 strategies (Borrelli et al., 2005). In a more recent study, only 5.5% of the 128 studies reviewed by Tucker and Blythe reported assessment of treatment fidelity (Tucker & Blythe, 2008).

Even after the CONSORT work group called attention to reporting details regarding delivery of interventions (Altman et al., 2001), less than 4% of intervention studies published in 6 psychological and psychiatric journals reported treatment fidelity data (Perepletchikova, Treat, & Kazdin, 2007). Therefore, it is fairly apparent from these reviews that the state of intervention fidelity assessment has not substantially improved over the past three decades. This finding seems applicable across diverse behavioral intervention studies, ranging from psychotherapy to applied behavior research. This provides compelling evidence that despite greater awareness of the importance of intervention fidelity, intervention fidelity is still not adequately reported, and likely also not adequately evaluated. This insufficient evaluation of intervention fidelity might be a consequence of discrepancies in the conceptualization of intervention fidelity (e.g. definition) and the complexity of operationalizing and evaluating fidelity in specific interventions.

There is still much debate regarding the conceptualization of intervention fidelity and the appropriate methods for evaluating fidelity within an intervention trial. Initially, intervention fidelity was focused only on whether the treatment or intervention was delivered as intended (Bellg et al., 2004; Borrelli et al., 2005; Moncher & Prinz, 1991). Intervention fidelity was generally conceptualized as the degree of adherent and competent delivery of an intervention (adherence and competence) by the interventionist as set forth in the intervention protocol (Santacroce et al., 2004). Adherence refers to the degree to which an intervention is implemented as intended, with an interventionist implementing all prescribed elements and avoiding proscribed elements or approaches (Hogue, Liddle, Singer, & Leckrone, 2005; Santacroce et al., 2004; Waltz et al., 1993). Competence refers to the extent to which the interventionist displays skill in utilizing core intervention approaches and responding to the individual needs of each participant (Santacroce et al., 2004; Tucker & Blythe, 2008). Moncher & Prinz (1991) agreed that adherent and competent delivery of an intervention is key, but added that treatment differentiation-- “whether treatment conditions differ from one another in the intended manner such that the manipulation of the independent variable occurred as planned”—is also critical (Moncher & Prinz, 1991, p. 247). Later, Lichstein and colleagues (1994) argued that two components: treatment receipt (whether the participant understands the skills learned during the session), and treatment enactment (whether the participant uses the skills in his or her daily life) must be assessed in order to form a complete treatment fidelity guideline.

To date, a universally accepted conceptualization of intervention fidelity has not yet emerged. This may be a reasonable explanation for why inconsistencies in operationalizing (e.g. implementing and evaluating) fidelity still exist. Multiple methodologies for implementing and evaluating fidelity have been developed since the mid-1980s (Dusenbury, Brannigan, Falco, &

Hansen, 2003); however, a standard methodology for implementing and evaluating fidelity within specific studies has not emerged.

A number of guidelines for implementing and evaluating fidelity have been developed on the basis of works by the previously noted researchers involved in fidelity conceptualization. In general, these guidelines can be classified into two categories. The first category includes guidelines which focus only on components that help ensure thorough delivery of the intervention (e.g. specification and standardization of interventions in manuals or study design, provider training, and monitoring of intervention delivery) (Carroll et al., 2000; Moncher & Prinz, 1991; Santacrose et al., 2004). The latter category goes beyond delivery to include other concepts (e.g. receipt, enactment, and participant responsiveness) in addition to intervention delivery (Bellg et al., 2004; Dane, & Schneider, 1998; Lichstein et al., 1994). An overview of the two categories of guidelines follows.

Moncher and Prinz (1991) were the first group of researchers who officially proposed a guideline for the enhancement of intervention fidelity. Based on their recommendations, researchers need to address two major questions: (1) integrity: was the intervention or treatment delivered as intended? and (2) differentiation: did the intervention or treatment conditions differ between groups in the intended manner? Both questions need to be addressed when evaluating fidelity because it is possible for interventions or treatments to be different (high differentiation) but still not be implemented as intended (low integrity), or for particular interventions or treatments to have high integrity but include overlap between groups (low differentiation). To effectively address these two issues, attention to the following components is required: (1) treatment definition (e.g. specification of the manipulated variable, distinct elements of each treatment, common elements across treatments, and the number and length of intervention

sessions), (2) interventionist training (e.g. interventionist's qualifications, composition of training sessions, ongoing supervision and feedback from the intervention supervisor), (3) fidelity-promoting procedures (e.g. procedures that maximize levels of fidelity such as ongoing supervision plan and deployment of manuals that provide a detailed description of the intended intervention procedures and restrictions), and (4) methods of verification and utilization of fidelity information including a specific plan for documenting that all aspects of the intervention were delivered as described (e.g. the intensity and length of intervention, occurrence of sessions) and measuring fidelity using a reliable and valid measure so that a fidelity assessment can be reported and analyzed in relation to the intervention outcomes. In summary, this guideline emphasizes only the components that help ensure thorough delivery of the appropriate intervention to each study participant.

Lichstein, Riedel, and Grieve (1994) recommended a fidelity guideline whereby adequate levels of three components are prerequisite to ensuring a valid clinical trial: delivery, receipt, and enactment. Unlike Moncher & Prinze, this guideline underlines the importance of both delivery of the intervention and the participant response. This includes assessing the degree to which (1) the intervention was delivered as intended (which embraces all components related to delivery of the intervention including study design, provider training, and monitoring of the delivery of the study), (2) the participant understood and used knowledge of treatment skills during the intervention session (receipt), and (3) the participant applied the skills in his or her daily life (enactment).

In 1998, Dane and Schneider (1998) introduced guidelines for implementing and evaluating fidelity composed of five components. They purport that when implementing and evaluating intervention fidelity, five components need to be taken into consideration: (1)

adherence (the extent to which the intervention elements were consistently delivered as described in the intervention manual), (2) dosage or exposure (how much of the intervention was delivered as planned, how many sessions of the intervention were delivered, how long was each session, and how frequently were intervention or treatment techniques delivered), (3) quality of the intervention delivery (how well was the intervention conducted based on qualitative aspects of intervention delivery that were not directly related to the delivery of prescribed content [e.g. interventionist enthusiasm, attitudes toward intervention]), (4) participant responsiveness (the degree to which the intervention stimulated the interest of participants or the degree to which participants were engaged [e.g., were participants attentive during intervention sessions?]), and (5) program differentiation (the extent to which an intervention's theory and practices can be differentiated from other interventions). In summary, this guideline places importance on implementing and evaluating fidelity on both delivery of the intervention and the participant response. However, it should be noted that the participant response in this guideline is limited to the interest of participants or the degree to which participants are engaged during intervention sessions, rather than the degree to which the participant understands and uses knowledge of treatment skills during the intervention session, and assessing the degree to which the participant applies the skills in his or her daily life as defined in other guidelines.

Perhaps the three guidelines that most comprehensively address the methodologies necessary to operationalize fidelity are the Behavior Change Consortium (BCC) treatment fidelity recommendations (Bellg et al., 2004; Resnick, Bellg et al., 2005), the guideline developed by Carroll and colleagues (2007), and the technology model of psychotherapy research (Carroll et al., 2000; Santacroce et al., 2004; Waskow, 1984). The BCC recommendations regarding treatment fidelity were developed based upon the Lichstein team's

(1994) model, which earlier in this paper is shown as including three components, but was specifically delineated by this group with five components as follows: (1) study design; (2) training providers; (3) delivery of treatment; (4) receipt of treatment; and (5) enactment of treatment skills. The design component consists of factors that should be taken into account when designing a study but also includes factors that should be reported so that evaluation and replication of the study are feasible. For instance, factors important to the design component include information about the underlying theory on which the intervention is based, information about content and dose (e.g. length of each intervention session, number of intervention sessions) for both the experimental and control groups and information on the interventionist's qualifications needed to effectively deliver the intervention (e.g. credentials, clinical background). The training component of the guideline contains a number of factors that are imperative for interventions that involve delivery by interventionists: hiring interventionists who are qualified to deliver the intervention and also knowledgeable about the intervention theory, information about the training program (e.g. whether training was standardized across interventionists, training evaluation, training supervision, skill maintenance). The treatment or intervention delivery component involves processes that monitor the delivery of the intervention to ensure that the intervention was delivered as planned; for example, development and implementation of a fidelity monitoring tool, recording the number of intervention sessions, assessment of the intervention delivery through audio-taped sessions. The receipt component focuses on evaluating whether the intervention has been received and understood by the participant by gauging that participants are able to understand the skills taught during the intervention session. The enactment component focuses on monitoring the ability of participants



to perform the learned skills in their daily lives (e.g. assessing whether the participants complete food diaries, examining whether the participants fills a pill organizer).

Carroll and colleagues (2007) developed guidelines for fidelity evaluation that were similar to those recommended by Lichstein et al. (1994), Dane and Schneider (1998), and the BCC group but differed in the methods and processes required. They emphasized intervention adherence (to what extent interventionists adhered to the principles of the intervention as designed by its developers). Based on their guideline, the key for evaluating fidelity focuses on the degree to which the intended content of an intervention is implemented. As a result, four major components including content, frequency, duration, and coverage (dose) are required to form the completed fidelity guideline. Based on these components, this guideline appears to primarily focus on the delivery of intervention. However, the guideline suggests the level of fidelity may be affected by other variables such as intervention complexity, quality of delivery, and participant responsiveness. Intervention complexity has been reported to negatively affect intervention fidelity: high intervention fidelity is more difficult to achieve in a complicated intervention whereas a simple and well-defined intervention is more likely to be delivered with high fidelity (Carroll et al., 2007). Quality of delivery, defined as the extent to which a provider or an interventionist approaches a theoretical ideal in terms of delivering intervention content, is also related to the level of intervention fidelity. Based on this guideline, quality of delivery places importance on the appropriateness of the delivery process for accomplishing what was planned. The guideline also notes that poor intervention delivery can occur even if an intervention was delivered completely, in other words, all components delivered as planned. However, the guideline does not explicitly provide information on how one could measure with certainty the quality of delivery. Rather, it only recommends the provision of substantial training

materials and support (e.g. ongoing monitoring and feedback) to those delivering an intervention. Considering the guideline's recommendation, the quality of delivery component is comparable to the training component of those discussed previously. Participant responsiveness, which involves both individuals receiving the intervention and individuals responsible for delivering it, is one important factor that may affect intervention fidelity. For example, high levels of fidelity are expected if those responsible for delivering an intervention are passionate about it. Furthermore, the uptake of the intervention depends on its acceptance and compliance by those receiving it as well. In summary, the guideline suggested that these variables have potential to affect the implementation or delivery process. Therefore, these variables should be taken into account as moderators when examining the relationship between intervention fidelity and outcomes (Carroll et al., 2007).

The technology model of psychotherapy research (Carroll et al., 2000; Santacrose et al., 2004; Waskow, 1984), proposes guidelines to control unsystematic variation in the delivery of interventions and includes four key features: (1) manual development that includes explication and standardization of an intervention's elements; (2) training and supervision of interventionists to mold and expand the skills necessary for conducting an intervention; (3) monitoring of intervention delivery by including ongoing evaluation of an interventionist's behavior; and, (4) inclusion of the measurement in the analysis by specifying intervention fidelity as a covariate when examining intervention effects. An overview of each feature follows.

Santacrose and colleagues (2004) state that explication and standardization of an intervention's elements in a manual is important because the manual lays out the intervention theory, goals, and strategies for achieving these goals. A manual is to be useful in training and supervising interventionists for research, and in disseminating interventions in practice. The

content of an effective manual should include important aspects of the delivery of the intervention such as an overview of topics to be addressed, the activities to be conducted, frequency, duration, and number of sessions, and mode of delivery. Training and supervision can be achieved through manual review, didactic seminars, and role-play experiences. Monitoring intervention fidelity also requires a measure that describes interventionists' behaviors (Santacrose et al., 2004; Waltz et al., 1993). Fidelity measures can be self-rated, but interventionists tend to over-report fidelity relative to reports given by independent raters (Carroll et al., 2000; Santacrose et al., 2004). For the fourth component of the technology model, "considering intervention fidelity in the analysis" is imperative. While traditionally intervention fidelity is not considered when evaluating the efficacy of an intervention, this means that intervention fidelity is not considered (Santacrose et al., 2004). Failure to consider whether the intervention has been delivered as assigned can lead to incorrect conclusions. The technology model also points out that including only intervention dose (e.g. the number of sessions attended by a participant) in a regression model does not adequately account for all of the variance in intervention delivery (Santacrose et al., 2004). This model recommends including the results from a valid and reliable measure of intervention fidelity in the regression model rather than a single item measure of dose. By including measures of intervention fidelity in the outcome analyses, the technology model enables a researcher to sort out any variances in outcomes that are due to poor intervention fidelity (Santacrose et al., 2004).

When comparing the three guidelines, there are two major differences between the BCC guideline, the guideline developed by Carroll and colleagues, and the technology model guideline. First, the BCC guideline and Carroll and colleagues' (2007) guideline include more components to construct the guidelines. As a result, both guidelines focus on interventionists'

behaviors and participants' behaviors (receipt and enactment or participant responsiveness). The second difference is that the technology model includes measures of intervention fidelity in outcome analyses (Carroll et al., 2000; Santacroce et al., 2004; Waskow, 1984) which is not emphasized or included in the BCC and Carroll and colleagues' models.

To summarize, all of the guidelines differ in whether or not they include participant responses as a part of fidelity, however, they are similar in terms of the need for clearly explaining, implementing, and evaluating the key elements of the particular intervention; training and supervision; and, monitoring of interventionists' behaviors to ensure the intervention is delivered as planned.

In the design of this current study, fidelity conceptualization focuses solely on intervention specification and delivery. While some guidelines include participant behaviors (receipt and enactment or participant responsiveness) (Bellg et al., 2004; Carroll et al., 2007; Lichstein et al., 1994), we believe these components relate to intervention effectiveness, but they are not components of intervention fidelity. Although the participant behaviors are important for understanding the efficacy of an intervention and the mechanisms through which they may have an effect, they are, in fact, outside the scope of intervention fidelity. A participant may be able to receive all elements of an intervention delivered with fidelity; nevertheless, she or he may not be able or willing to understand or apply them. We determined that intervention fidelity should focus purely on the *operationalization and delivery* of the intervention elements and focused on achieving results driven by the question-- Were those processes carried out as theoretically intended?

Our decision to use the technology model was also reinforced by the fact the BCC (Bellg et al., 2004) describes receipt of intervention as evaluating whether the intervention has been

received and understood by the participant, but it is not clear what “received” and “has been understood” means. A clear description of whether this means hearing what was said, understanding it cognitively, or accepting it attitudinally was not explicitly delineated by the authors. Additionally, it is difficult to distinguish between fidelity of enactment and adherence of participant to the intervention, and the BCC does not provide clear statements regarding this distinction. When receipt and enactment are not explicitly described, it is difficult to operationalize the BCC recommendations.

Like the BCC guideline, the guideline developed by Carroll and colleagues (2007) includes more components. However, this same guideline has at least one weakness. The guideline does not provide comprehensive strategies on how to assess some of the components, particularly the quality of delivery. This is further compounded by the fact that Carroll and colleagues define quality of delivery in a nearly identical way to how many other groups define intervention fidelity. Since little instruction is provided concerning how to measure this component, it might be too complicated to employ this guideline for monitoring or evaluating fidelity in any study.

In summary the technology mode is preferable for our purposes for a number of reasons. First, it includes components that pertain only to interventionists’ behaviors and second, it is simple, but comprehensive, and easy to use and/or follow. This model’s focus does not stray as some models do to include participant behaviors; the emphasis is clearly upon the interventionist’s behavior. As a result, the technology model was selected as a guideline deemed appropriate for developing a plan for monitoring and evaluating intervention fidelity for the WRITE Symptoms intervention (See the *“Conceptualization and operationalization of intervention fidelity for the WRITE Symptoms Intervention”* section for more details regarding

how the technology model was used as a guideline for ensuring fidelity in the WRITE Symptoms intervention).

### **1.2.2 A Written Representational Intervention to Ease Symptoms (WRITE Symptoms)**

WRITE Symptoms intervention was developed based on the Representational Approach to patient education (RA), an intervention theory developed by Donovan and colleagues (Donovan & Ward, 2001; Donovan et al., 2007). The RA integrates two complimentary theories regarding the structure of knowledge (Leventhal et al., 1997) and the processes through which knowledge changes with new information (Posner et al., 1982). It emphasizes assessment of a participant's individual representations of her health problem(s), prior to being provided any new information, as a way to facilitate the teaching/learning process. WRITE Symptoms is an eight week intervention that includes effective evidence-based elements of previous symptom management interventions and is delivered according to principles of effective computer-mediated interventions (Donovan et al., 2007; Dumrongpakapakorn, Hopkins, Sherwood, Zorn, & Donovan, 2009; Krishna, Balas, Spencer, Griffin, & Boren, 1997; Lorig, Ritter, Laurent, & Plant, 2006; Murray, Burns, See, Lai, & Nazareth, 2005; Wantland, Portillo, Holzemer, Slaughter, & McGhee, 2004). The WRITE Symptoms intervention follows the guidelines and seven key elements of the RA (Donovan et al., 2007) plus evidence-based recommendations for cancer symptom management in order to help women with ovarian cancer improve their symptom management. The specific elements of the WRITE Symptoms intervention based on the RA include:

*Element 1* (Representational assessment): Participants are asked to write about their target symptoms (up to three patient-selected symptoms—one symptom at a time). Probing is used as necessary to elicit participants' representations of their symptoms (identity [severity], cause, timeline, consequences, controllability, and emotional distress). By providing a detailed description of their symptoms, participants have the opportunity to examine and comment on the relationships among their representations, their current symptom management strategies and their functioning and QOL.

*Element 2* (Exploring concerns, misconceptions, and gaps): In the second step, participants are encouraged to think about any experiences that led to misconceptions or gaps in understanding about symptom management identified in the first step and to evaluate the strength or importance of the misconceptions. The goal is to understand how the participant developed any identified concerns, misconceptions or gaps and how strongly held these perceptions are.

*Element 3* (Creating conditions for conceptual change): In the third step, the participants are asked to discuss ways in which gaps or misconceptions she has may be contributing to inadequate symptom management. The goal of this step is to make direct links between the previously elicited gaps, confusions, or misconceptions and undesirable consequences of poorly managed symptoms. To achieve the goal, the interventionist is trained to confer with the participant regarding: (a) the relationship between identified concerns, misconceptions, or gaps and consequences of under-managed symptoms that participant discussed during representational assessment, (b) link between common concerns and consequences of under-managed symptoms if no concerns were presented, (c) information to address participant's concerns, misconceptions,

or gaps, (d) how new ways of approaching symptom management could solve some of current problems.

*Element 4* (Introducing new information): In the fourth element, because participants' symptom representations have been elicited, the interventionist can present new information about symptoms and symptom management in a contextual manner such that it can be seen as an intelligent and plausible solution to problems associated with their current representations. In this step, the participants are provided with the best symptom management information available from research and clinical practice guidelines to help them feel more comfortable and confident in discussing symptoms and to learn about different strategies for managing symptoms.

*Element 5* (Summary): In the fifth element, a discussion of the benefits of learning and acting on the new information (conceptual change) is intended to promote acceptance of new information.

*Element 6* (Goal setting & strategy selection): Based on new information, the participants are asked to develop symptom goals and highly individualized symptom management strategies based on information provided. Participants are then asked to spend two weeks implementing those strategies.

*Element 7* (Strategy review & revision): Participants are asked to evaluate the strategies that they attempted to implement and discuss any revisions to the plan that they feel are necessary.

Examples of statements used for each element of the RA are given in Table 1.



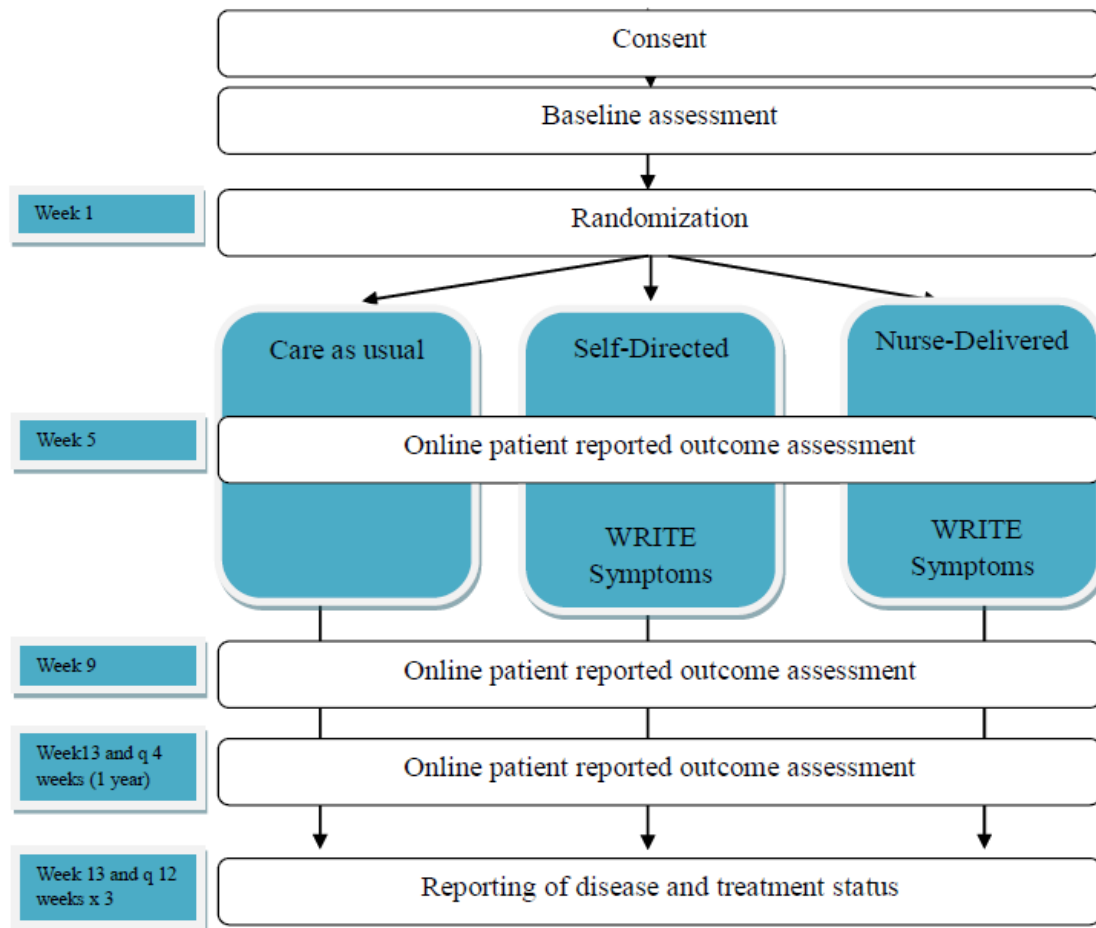
**Table 1 Examples of statements used for each element of the RA**

Element	Example
1. Representational assessment	Assessment questions begin with very broad, open-ended questions such as “I want to understand more about your pain, could you please tell me more about the pain that you’ve been having lately?”. Nurses are then expected to use specific probes related to elements of representations that were not spontaneously offered after open-ended questioning. Examples of the specific questions related to each element of representations include (1) What does your pain feel like and how severe is it? (Identity), (2) What do you think is causing your pain? (Cause), (3) When did you first notice it and does it follow any sort of pattern? (Timeline), (4) How has the pain affected your life? (Consequence), (5) What are you doing or have you tried in the past to manage/control your pain? (Cure/control), and (6) How does it affect you emotionally? (Emotion).
2. Exploring gaps, concerns, and misconceptions	I am wondering about the pain you have during the night. You said that you don’t like taking pain medicine. Can you tell me more about that? What concerns do you have about taking pain medicines? Have you had any problems taking pain medicine for arthritis in the past?
3. Creating conditions for conceptual change	It seems that you try not to take pain medicine, and the pain you are experiencing later in the night prevents you from getting the sleep you need to feel rested and comfortable. My hope is that we can find some new strategies to reduce your pain so that you can have more energy to do the things you want, like grocery shopping and the important work for your church.
4. Introducing new information	There are many strategies that come from research and best clinical practice that we’ve pulled together into the Symptom Care Guide for pain. It contains a lot of information on things that might help your pain. You might find some ideas that you can put to use in your own life. Please read through the Guide and think about whether any of them might be helpful to you. We can talk about them in more detail here on the message board.
5. Summary	Here is what we have been talking about over the past several messages. We discussed your pain and how it affects your ability to do your daily activities. We also talked about some of your concerns and how we want to be sure concerns are not getting in the way of the best care you can get. You really took the time to think and read and consider what types of strategies would fit best in your own life. That’s such an important part of this process!
6. Goal setting & strategy selection	<p>You mentioned earlier how much you miss playing with your granddaughter due to so much pain. What is a specific goal you could set as a way to get playtime scheduled with her?</p> <p>There’s information in the Symptom Care Guide that is helpful and includes:</p> <ul style="list-style-type: none"> <li>- Taking pain medicines as prescribed. The best way to take medicines is on a schedule (e.g., every 4 hours, “around-the-clock”). Waiting until the pain returns means you will have to play “catch up.”</li> <li>- Take supplemental, or as-needed, pain medicines before any activity you know will be painful.</li> </ul> <p>So, (participant’s name), select the strategies that make sense to you and consider these as steps you want to take to reach your pain management goal and your activity level goal, too.</p>
7. Strategy review & revision	<p><b>Strategy review</b></p> <p>It’s time for us to touch base about your new strategies over the last 2 weeks. The strategies you planned were: (list strategies). I’m curious to know how things have gone. For each strategy, please tell me as much as you can in response to these questions: Were you able to use the above strategies? If not, what things prevented you from doing so? If yes, how well did the strategies (name/list strategies) work in helping you reach your goal of “(list goal)” Did you experience any problems or concerns as a result of any of these strategies?</p> <p><b>Strategy revision</b></p> <p>I have a good picture of what is going on with you pain-wise... and you seem very aware of what is working and what is not. I’m glad you are feeling better. I trust that’s encouraging to you.</p> <p>I can see you are making modifications to your plan. That’s great. I’ll make it "official" on the <i>Pain Review</i> care plan. Look under the <i>My Symptom Care Plan</i> tab to be sure I got it right. I’ll put the updates in <b>bold</b>. I like that your plan includes different kinds of strategies and ways to approach managing your problems. Do you want to make Tylenol an "as needed" strategy.... just use it when you anticipate more discomfort or pain? Do you want to drop strategy no.3 but keep no.4? Symptom management changes over time... you’ll find you need to assess and modify your plan, like seasoning a meal to taste, so you enjoy life as best you can. You’re doing a great job.</p>

One of the innovative aspects of WRITE Symptoms, compared to previous RA interventions, is that it uses a web-based delivery system specifically designed to support nurse-participant interactions. The nurse and participant communicate via asynchronous postings to

the participant's private message board. The research nurse leads the participant through the seven elements of the RA and the participant can engage in the intervention from the comfort of her own home, at times convenient to her. The nurse coaches the participant through the WRITE Symptoms intervention in order to develop individualized goals and strategies to help her better manage her multiple symptoms.

Findings from a pilot study of 65 women with recurrent ovarian cancer suggested that the nurse-delivered WRITE Symptoms is a feasible, acceptable intervention, with preliminary evidence supporting improvements in symptom representations (Donovan et al., 2008). However, an important question still remains whether the success of the intervention is dependent on individualized coaching by nurses, or whether its success could be accomplished by implementing a web-based, interactive computer module without a nurse interventionist. Therefore, a three-arm randomized clinical trial (RCT) is currently being conducted to compare the efficacy of the two different web-based delivery systems (nurse-delivered via private web-based message boards versus self-directed using a web-based computer module) versus usual care in a sample of 480 women with recurrent ovarian cancer recruited from Gynecologic Oncology Group sites across the United States (GOG0259; NIH NR010735). The two WRITE Symptoms interventions (nurse-delivered WRITE Symptoms and self-directed WRITE Symptoms) are structured by the RA.



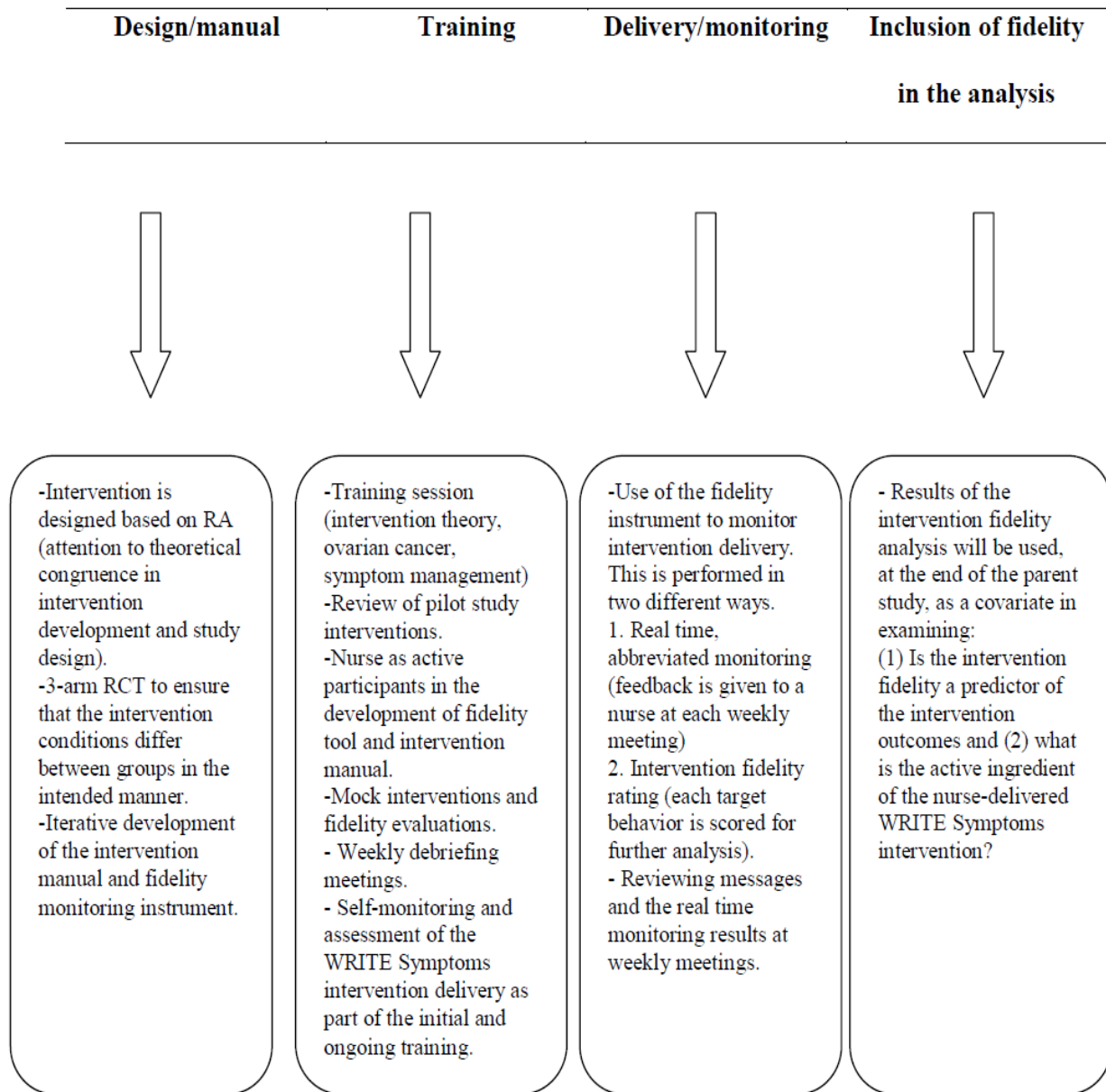
**Figure 1 WRITE Symptoms study schema**

As an RCT, the WRITE Symptoms study is designed to control as many sources of bias as possible. After assessment of eligibility and recruitment, the study participants are randomly allocated to nurse-delivered WRITE Symptoms, self-directed WRITE Symptoms, or care-as-usual. Dependent variables are evaluated monthly for 12 months for participants in all three groups. (See Figure 1 for the study schema.) The RCT design of the WRITE Symptoms study is one important factor for ensuring that changes in the study outcomes are the result of a systematic manipulation of the intervention and not due to other random factors. However, to

ensure that the findings from the WRITE Symptoms RCT are valid, we must also protect against poor intervention fidelity, a major threat to internal validity (Shadish, Cook, & Campbell, 2002).

### **1.2.3 Conceptualization and operationalization of intervention fidelity for the WRITE Symptoms Intervention**

To ensure fidelity to the WRITE Symptoms intervention and to optimize validity of findings at the conclusion of the study, we have developed a comprehensive plan for monitoring and evaluating intervention fidelity. In this study, we define fidelity as the degree to which treatments or interventions have been delivered as planned (Bruckenthal & Broderick, 2007; Carroll et al., 2007; Tucker & Blythe, 2008; Wilkinson, 2006, 2007). Our fidelity conceptualization focuses on interventionists' behaviors. Consequently, we embrace the technology model and its four key components: (1) manual or design (to ensure congruence with the underlying theory); (2) training (to ensure that interventionists are qualified and consistently trained); (3) monitoring (to ensure the intervention is delivered as intended); and, (4) inclusion of the fidelity measurement in the analysis of intervention efficacy. Inclusion of the fidelity measurement in analyses of intervention efficacy as recommended by the technology model will help us understand how the intervention produces its effects. This model may allow us to answer important questions such as whether or not fidelity to the intervention influences outcomes and what elements of the intervention are the essential, active ingredients. Ultimately, we may be able to identify ways to refine the WRITE Symptoms or other RA interventions in the future. The conceptual model guiding the intervention fidelity plan for the WRITE Symptoms intervention is depicted in Figure 2.



**Figure 2 The conceptual model guiding intervention fidelity evaluation in this study**

NOTE: Following the technology model, we addressed all four components of fidelity evaluations: (1) Design/Manual, (2) Training, (3) Delivery Monitoring, and (4) Inclusion of

fidelity in analyses. This doctoral student had primary responsibility for operationalizing fidelity to the WRITE Symptoms intervention and conducting preliminary evaluations of the instrument (critical work in preparation for the delivery monitoring component). The original study design, manual development, and interventionist training were directed by the PI of the original study (Donavan). The doctoral student was actively involved in these components as a member of the research team. Finally, the fourth component of intervention fidelity, inclusion of fidelity evaluations in the analysis, is described in the “results: analytic plan” section.

#### **1.2.4 Significance of the study**

The proposed study will provide guidelines for implementing and evaluating fidelity in the WRITE Symptoms study and play an important role as an exemplar of how to design a fidelity instrument and evaluate fidelity in (1) other web-based psycho-educational interventions, and (2) other RA-based interventions. Concerning the latter scenario, the RA has been integrated into a number of intervention studies. Although each study tailors the RA to the unique context of diseases and disease conditions present in their populations, the instrument developed to monitor and evaluate the delivery of the WRITE Symptoms intervention may also have high applicability for other RA-based interventions. In addition, development of a fidelity instrument and a comprehensive fidelity plan for the nurse-delivered WRITE Symptoms intervention will also enhance the credibility of the intervention by increasing consistency of the intervention delivery and maximize validity of the study. In the event that the intervention outcomes are as favorable as hypothesized—that is, the nurse-delivered intervention is shown to be more effective relative to the other two arms of the study-- dissemination and translation of the intervention into clinical settings will be the next step in this program of research. The fidelity tool, intervention manual,

and comprehensive fidelity plan developed for this study will help to ensure accurate dissemination of the intervention and increase the likelihood of successful adoption by clinicians.

Therefore, the aims of this study are to (1) develop and refine the WRITE Symptoms fidelity instrument, (2) evaluate the reliability of the WRITE Symptoms fidelity instrument, (3) establish a fidelity monitoring plan for a large multisite RCT of the WRITE Symptoms intervention, and (4) develop an analytic plan to understanding the influence of fidelity on the intervention outcomes. Research questions to be addressed by this study are:

1. What are the essential specific and non-specific intervention components to be included in the WRITE Symptoms fidelity instrument?
2. Is the WRITE Symptoms fidelity instrument a reliable measure of intervention fidelity as evidenced by: (1) inter-rater reliability and (2) intra-rater reliability (test re-test reliability)?
3. What is the fidelity monitoring plan for the WRITE Symptoms intervention?
4. What is the analytic plan to understanding the influence of fidelity on the intervention outcomes:
  - a. Is intervention fidelity a predictor of intervention outcomes (symptom severity, symptom consequences, and symptom distress)?
  - b. What are the active ingredients of the nurse-delivered WRITE Symptoms intervention?

## **2.0 METHODS**

### **2.1 PARENT STUDY**

This study is part of an ongoing clinical trial examining the efficacy of two different web-based symptom management interventions compared to care-as-usual in a sample of 480 women with recurrent ovarian cancer recruited from Gynecologic Oncology Group sites across the United States (GOG0259-The WRITE Symptom Study). This study is focused only on the nurse-delivered WRITE Symptoms arm to which 160 participants will ultimately be randomly assigned. The nurse-delivered WRITE Symptoms is delivered via private web-based message boards while the self-directed WRITE Symptoms is delivered via an interactive web-based computer module. Primary outcomes of the parent study are symptom representations (severity, distress, and consequences), quality of life, and depression. Participants in the WRITE Symptoms study are women with recurrent ovarian cancer attending Gynecologic Oncology Group (GOG) clinics across the country. Eligible participants include all women with recurrent ovarian, fallopian, or primary peritoneal cancer who are experiencing at least 3 symptoms from their disease or treatment, have GOG performance status scores greater than 3, and are able to read and write English. Participants who do not have access to computer and Internet are provided with netbooks and 3G Internet access. The study protocol has been reviewed and approved by the centralized Human Subjects Committee at the Gynecologic Oncology Group,



the University of Pittsburgh Institutional Review Board (as the coordinating center), and each participating clinic's institutional IRB. Details of the parent study are provided in section 1.2.2.

## **2.2 AIM 1: TO DEVELOP AND REFINE THE WRITE SYMPTOMS FIDELITY INSTRUMENT**

To address Aim 1, four important processes were conducted, including: (1) item generation, (2) item selection, (3) item scaling, and (4) preliminary item testing.

### **2.2.1 Item generation**

Generation of initial items was based on an extensive review of the fidelity literature and the RA theory. When developing an intervention manual and fidelity instrument, it is crucial to identify types of interventionist behaviors that are proscribed and prescribed for a particular study (Calsyn, 2000; Waltz et al., 1993). Following recommendations by Calsyn (2000) and Waltz and colleagues (1993) and taking the uniqueness of WRITE Symptoms intervention into account, two research members (the PI [HD] and the doctoral student [PD]) identified four types of behaviors deemed essential for the successful delivery of the WRITE Symptoms intervention to include in the fidelity instrument (See Chapter 5 "Training Manual" section). Then, the items were generated directly from the theoretically-guided elements of the WRITE Symptoms intervention as described in the study protocol, the intervention manual, and analysis of five intervention sessions selected from a pilot study of the WRITE Symptoms intervention. Drafts of the instrument were discussed and revised until consensus between the two research members

was reached. Then, other research team members (PhD prepared participant coordinator [JK] and nurse interventionists) reviewed and compared the draft with the intervention manual to verify congruence between the study protocol and the instrument.

### **2.2.2 Item selection: content validity and item clarification**

In the first stage of item selection, we focused on establishing item clarity and content validity. The initial instrument was reviewed by a panel of five experts in fidelity assessment and the RA. All experts were PhD prepared (four are nurses and one is a social worker). They all worked extensively on developing and evaluating representational approach-based interventions. All had performed intervention fidelity evaluation; one had published a manuscript on fidelity. Advice from the experts focused on item clarity and how well the instrument identified behaviors that were unique and essential to the intervention as well as general behaviors essential and common to most psycho-educational interventions. Their responses led to concurrent refinement of the fidelity instrument and the intervention manual (See more detail in Chapter 4 “Results Manuscript: Development and Testing of the WRITE Symptoms Fidelity Instrument”). As a result of the iterative process, the number of items was reduced to 62 items.

### **2.2.3 Item Scaling**

Both Likert-type scales and dichotomous responses were considered as item scaling. Compared to Likert scaling, dichotomous scaling is more likely to achieve greater inter-rater reliability (Waltz et al., 1993); however, it does not allow for capturing completeness or extent of the required behavior performed by the interventionist. Initially, we used a 5-point Likert format

based on the Yale Adherence and Competence Scale (YACS) (Carroll et al., 2000). Whereas the 5-point Likert scale provides an advantage over dichotomous scaling in capturing discrete levels of completeness or extent of the behavior performed by the interventionist (Waltz et al., 1993), our preliminary pilot testing of the initial instrument discovered its disadvantages as mentioned in previous studies -- that the response options of a 5-point Likert scale are difficult to operationalize (Waltz et al., 1993). A Likert-type scale can lead to a large degree of subjectivity in the ratings and is more likely to negatively influence inter-rater reliability (Waltz et al., 1993). We found it difficult to reach agreement using the 5-point Likert-type scale. Consequently, to make the instrument more practical, easier to use, and possibly increase inter-rater reliability and decrease subjective interpretation of the individual items between raters in future use, we reduced the number of response options to a 3-point Likert-type scale. Raters are asked to respond to items that ask whether a nurse engaged in a particular behavior (e.g., Did the nurse assess the participant's perception of the cause of her symptom?). Response options are 0 (not at all); 1 (Some); 2 (Completely).

#### **2.2.4 Preliminary item testing**

A sample of five mock interventions generated during interventionist training was used to evaluate inter-rater reliability (percentage of agreement (POA) between two raters: HD and PD) for individual items and the full instrument. POA, at this stage, was calculated by having the total number of ratings (of each subscale) for which both raters agree (number of agreement) divided by the total number of ratings made by each rater (total number) and then multiplied by 100. Below is an example of how the POA was calculated for a subscale with 6 items:

Total number = 6 items x 5 mock interventions = 30

Number of agreement = 27

POA =  $(27/30) \times 100 = 90$

## **2.3 AIM 2: TO EVALUATE THE RELIABILITY OF THE WRITE SYMPTOMS FIDELITY INSTRUMENT**

### **2.3.1 Sample**

This phase of evaluation used posts extracted from the first completed intervention sessions (N = 20) from the nurse-delivered intervention arm.

#### **2.3.1.1 Sample size justification**

The sample size justification was calculated based on recommendations from previous studies which indicate that the minimum sample size required for the valid application of weighted kappa can be estimated by the simple formula  $2k^2$  (where  $k$  is a number of categories of classification) (Cicchetti, 1981; Cicchetti & Fleiss, 1977). In this study, this formula produces sample size that equals to 18 (when  $k = 3$  [“0” = not at all; “1” = some; and, “2” = completely]).

#### **2.3.1.2 Inclusion criteria**

To be considered a “completed” intervention session for the purposes of evaluating intervention fidelity, the session must demonstrate that each pair of a participant and a nurse interventionist finished working on at least two symptoms. If any sessions had all three symptoms completed,

every first symptom was selected, and either the second symptom or third symptom was randomly selected for evaluation. The first symptom was always selected because it contained more details of the RA process while the second or third symptoms was required because it allowed a rater to assess whether the interventionist is able to reintroduce and turn over the RA process to the participant during the discussion of the second or third symptoms. See more details regarding the inclusion criteria in Chapter 4 “Results Manuscript: Development and Testing of the WRITE Symptoms Fidelity Instrument”.

### **2.3.2 Instrument: WRITE Symptoms fidelity instrument**

The full instrument is provided in Appendix A. The instrument includes 54 items in 13 subscales. Response options are based on a 3-point scale. Raters evaluate the extent to which an interventionist performs target behaviors. Each item is rated on a scale of “0” = not at all; “1” = some; and, “2” = completely.

### **2.3.3 Rater selection and training**

Proper training of the raters is essential to guaranteeing reliable utilization of the instrument. Scoring of intervention sessions is a complex task requiring expertise comparable to that of the study interventionist so it is essential that raters have knowledge and experience related to the intervention (Carroll et al., 2000; Moras & Hill, 1991). For this study, the raters included three doctoral students. The raters were knowledgeable about the RA and the WRITE Symptoms intervention in addition to being educated about ovarian cancer and symptom management. All raters underwent specific training, including didactic lectures on the theoretical underpinnings

and specific elements of the intervention (by the RA developer: HD), and independent reading and group discussion of the RA, the WRITE Symptoms study, and the intervention manual. Every rater was provided a copy of the fidelity tool, the process for rating intervention sessions, and examples of intervention sessions and scores rated by experienced raters (HD and PD) as exemplars of the typical way of administering the score to familiarize all raters with use of the instrument. Then, the raters were trained to rate intervention sessions. Training consisted of three 2-hour practice sessions. During each session, the raters performed the measures on a mock intervention session, discussed the intervention, and requested additional clarification from HD when discrepancies in scorings remained after discussion. Once all raters felt comfortable with the instrument and scoring procedures, the raters were requested to score one additional intervention session. Scores were compared with those from HD and PD, and if discrepancies were found, more instruction and practice were provided for calibration. Eighty percent (80%) of POA or concurrence reached was deemed as satisfactory. POA, at this stage, was calculated by having the total number of items on which both raters agree (number of agreements) divided by the total number of items (54) and then multiplied by 100.

#### **2.3.4 Procedure**

The first twenty (N = 20) completed intervention sessions from the nurse-delivered intervention arm were evaluated. The entire set of interactions on the nurse-participant message board was extracted from the WRITE Symptoms database. All posts related to two symptoms were selected for the fidelity analysis. In order to avoid the risks of rating bias specific to this intervention (there are only 4 interventionists and personal anecdotes are often included in the messages), several steps were taken. The participant's name, the nurse interventionist's name, and any

relevant information that could unblind the rater to the identity of the interventionist (such as where the interventionist lives, reference to their family) were de-identified to prevent bias. Each intervention session was also given a unique ID in order to prevent rating bias. Then the raters rated the selected intervention sessions as described in the next paragraph.

For *inter-rater reliability*, the intervention sessions were rated independently by two raters (KW and PD or TH and PD) using the WRITE Symptoms fidelity instrument. Items were read and then scored on the basis of how extensively the interventionist performed the target behaviors (“0” = not at all; “1” = some; and, “2” = completely). For *intra-rater reliability*, the raters rated the same set of the twenty messages a second time, two weeks after their first rating. Two weeks is a recommended timeframe to prevent carry-over effects (Bailar & Mosteller; 1992).

### **2.3.5 Data analysis and interpretation**

Completed fidelity evaluations were returned to PD for analyses and entered into a dataset consisting of fidelity scores for each item from each independent rater. Analyses included inter-rater reliability assessed by two raters and intra-rater (two week-test retest) reliability. Weighted Kappa statistics and POA were calculated to examine inter-rater reliability for each intervention session (N=20) between each pair of raters (either PD and TH or PD and KW). Kappa statistics and POA were also calculated to examine intra-rater reliability for agreement of scoring from each intervention session (N=40) for the same person at two different time points.

Although using POA to calculate reliability provides some benefits due to its computational simplicity and ease of interpretation, it has significant disadvantages (Watkins &

Pacheco, 2000). POA values represent total agreement without any consideration given to the operation of chance (Landis & Koch, 1977; Watkins & Pacheco, 2000). The Kappa statistic, on the other hand, is a measure of true agreement, beyond that which is expected by chance (Cicchetti, 1994; Landis & Koch, 1977). While use of the intraclass correlation coefficients (ICC) is recommended for assessing overall scale inter-rater reliability when researchers have data of an ordinal, interval, or ratio level of measurement, Kappa is appropriate for establishing agreement by item (Rigby, 2000; Stein et al., 2007). The disadvantage of the Kappa statistic is that it tends to underestimate the level of agreement when the number of items is increased (Maclure & Willett, 1987). However, using the Kappa statistic may have benefits over using the ICC because being able to evaluate and identify individual specific problematic items is important at the early stages of instrument development.

Consequently, both POA and weighted Kappa statistic estimates were calculated for each item. The POA was calculated using this formula:  $(\text{Total number of interventions in agreement} / \text{Total number of interventions [20]}) * 100$ . The weighted Kappa statistic estimates were calculated using SAS statistical software (SAS Institute, Cary, NC, U.S.A.) (FREQ procedure, option AGREE). In this present study, we interpreted the level of rater agreement by using the five-level categorization recommend by Landis and Koch as the following: ‘slight agreement’ (Kappa values =0.0-0.2), ‘fair agreement’ (0.21–0.4), ‘moderate agreement’ (0.41–0.6), ‘substantial agreement’ (0.61– 0.8) and ‘almost perfect agreement’ (0.81–1) (Landis & Koch, 1977). Consideration was given to items with the Kappa statistics less than 0.61 for further revisions (See Chapter 4 in more detail).



## **2.4 AIM 3: TO ESTABLISH A FIDELITY MONITORING PLAN FOR A LARGE MULTI-SITE RCT OF THE WRITE SYMPTOMS INTERVENTION**

To ensure intervention fidelity in the nurse-delivered WRITE Symptoms intervention, a training manual was developed to be used along with the intervention manual instrument. The fidelity instrument and its associated manual are essential for addressing the four components of the technology model to ensure intervention fidelity. The manual was developed based on a review of the literature, the technology model and is specific to unique aspects of web-based delivery.

## **2.5 AIM 4: TO DEVELOP AN ANALYTIC PLAN TO UNDERSTAND THE INFLUENCE OF FIDELITY ON THE INTERVENTION OUTCOMES**

A plan for supporting exploratory analyses at the conclusion of the WRITE Symptoms study to evaluate the effect of fidelity on intervention efficacy was developed (see Chapter 6 “Results: Analytic Plan” section). The plan was based on a review of the literature and consultations with a statistician. Intervention fidelity will be used as one of the independent variables in evaluating the study outcomes at the end of study. Therefore, variability in delivery of the intervention can be evaluated as another factor influencing intervention efficacy. This will help researchers to have greater confidence in drawing conclusions regarding findings from the study that will be a result of the intervention and not due to other effects (Bellg et al., 2004; Santacroce et al., 2004).

## **2.6 HUMAN SUBJECT RESEARCH**

### **2.6.1 Responsible Conduct of Research**

All doctoral students are required to complete The University of Pittsburgh Education & Certification Program in Research & Practice Fundamentals, an on-line educational series designed to provide training to individuals employed by the University of Pittsburgh, and its affiliated institutions. The program consists of required and optional modules, depending on one's research focus. The doctoral student has completed four required modules including: 1) Research Integrity, 2) Human Subjects Research, 3) Human Subjects Research in Social and Behavioral Sciences, and 4) Privacy Requirements for Researchers under HIPAA. Upon completion of this program, a certification is stored in a database and the examinee is able to print out a hard copy of this certificate for their records and submission to the Public Health Service granting agencies.

The doctoral student has also gained knowledge of ethical issues related to human subjects' research which are incorporated in doctoral courses such as Research Methods, Qualitative Research, Grant Writing Practicum, Research Development, and Building a Program of research. Areas covered in these courses include ethical issues related to obtaining informed consent, participant confidentiality, conflict of interest, research integrity, protection of vulnerable subjects, and seeking IRB approval.

## **2.6.2 Protection of Human Subjects**

There were no physical risks associated with this study. Potential breaches to confidentiality were addressed by limiting access of study data to study personnel only. All information obtained from this study is kept confidential. All data collected on the secure website are not personally identifiable. All participants select a unique userid which is used to connect all of their information.

## **2.6.3 Women, Minority, and Children Inclusion in Research**

### **2.6.3.1 Inclusion of Women and Minorities**

This is a study for women; therefore, no eligible woman will be excluded based on race or ethnicity. Any eligible person who would like to participate, but does not have access to computer or Internet will be provided access for the full year of study participation.

### **2.6.3.2 Inclusion of Children**

Target enrollment for the WRITE Symptoms study is 480 women with recurrent ovarian cancer who are experiencing at least 3 symptoms from their disease or treatment. Based on previous studies by this group, the research team expects to enroll women aged 30 - 90; however, the study will not exclude any women age 18 or older based on age.

#### **2.6.4 Data Safety and Monitoring Plan**

Data and safety monitoring were conducted during meetings with the dissertation committee. During these meetings, confidentiality issues were addressed. To maintain confidentiality of research records, the participant's name, the nurse interventionist's name, and any relevant information (such as where the interventionist lives, reference to their family) were de-identified. There were no breaches in confidentiality during the course of this study.

### 3.0 SUMMARY OF DISSERTATION FINDINGS

The purpose of this study was to provide guidelines for implementing and evaluating fidelity in the WRITE Symptoms study and play an important role as an exemplar of how to design a fidelity instrument and evaluate fidelity in (1) other web-based psycho-educational interventions, and (2) other RA-based interventions. The specific aims were to (1) develop and refine the WRITE Symptoms fidelity instrument, (2) evaluate the reliability of the WRITE Symptoms fidelity instrument, (3) establish a fidelity monitoring plan for a large multisite RCT of the WRITE Symptoms intervention, and (4) develop an analytic plan to understand the influence of fidelity on the intervention outcomes.

The specific aims were addressed in three RESULTS sections. The manuscript entitled *“Development and testing of the WRITE Symptoms fidelity instrument”* addressed the first and second aims by providing information regarding the essential specific and non-specific intervention components to be included in the WRITE Symptoms fidelity instrument and psychometric properties of the instrument. The third aim, to establish a fidelity monitoring plan for a large multisite RCT of the WRITE Symptoms intervention, was addressed in the results *“training manual”* section. And, the fourth aim, to develop an analytic plan to understand the influence of fidelity on the intervention outcomes, was addressed in the results *“analytic plan”* section.

**Research question # 1:** What are the essential specific and non-specific intervention components to be included in the WRITE Symptoms fidelity instrument? As addressed in the manuscript (phase 1), the WRITE Symptoms fidelity instrument is composed of four types of behaviors deemed essential for the successful delivery of the WRITE Symptoms intervention in the fidelity instrument: (1) essential and unique (behaviors that are essential to the WRITE Symptoms interventions but are not expected to be found in other types of interventions); (2) essential but not unique (behaviors that are essential to the WRITE Symptoms interventions but not unique to them); (3) proscribed (behaviors that should not occur in any of the WRITE Symptoms intervention sessions); and (4) necessary for asynchronous web-based interventions (behaviors that considered essential in conducting asynchronous web-based interventions). The initial 62 item instrument demonstrated acceptable psychometric properties in preliminary evaluations. The POA for the full instrument ranged from 82.69 to 94.23 across interventions. Minor clarifications and refinements were necessary. Several items were deleted based on redundancy and/or low reliability; others were modified to clarify language; and others were split into two questions. One item was removed later during rater training process due to redundancy. See Appendix A for the final 54-item fidelity instrument.

**Research question # 2:** Is the WRITE Symptoms fidelity instrument a reliable measure of intervention fidelity as evidenced by: (1) inter-rater reliability and (2) intra-rater reliability? Based on its inter-rater reliability and intra-rater reliability, the WRITE Symptoms fidelity instrument demonstrated acceptable psychometric properties. Inter-rater reliability based on weighted Kappa range from 0.47 to 1.00 and percentage of agreement (POA) range from 85 to 100 for each individual item. Intra-rater reliability was also good with weighted Kappa of 0.48 to 1.00 and POA of 85 to 100 for each individual item. Overall weighted Kappa statistic for the

instrument was 0.83. For intra-rater reliability, overall weighted Kappa statistics for each subscale were between 0.66 and 0.96. Overall weighted Kappa statistic for the instrument was 0.93. This instrument is promising for the fidelity assessment of the nurse-delivered WRITE Symptoms intervention, and its use in further research is warranted.

**Research question # 3:** What is the fidelity monitoring plan for the WRITE Symptoms intervention?

To address the third research question, a manual was created to describe how to use the fidelity instrument to monitor fidelity of the nurse-delivered WRITE Symptoms intervention. Content include (1) how to train interventionists and (2) how to train raters to use the instrument. The manual provides specific guidelines on using the instrument to train nurses initially and ongoing through refresher training; assessing the qualifications of raters; training raters; coding rules for each of the 54 items.

**Research question # 4:** What is the analytic plan for understanding the influence of fidelity on intervention outcomes?

(a) Is intervention fidelity a predictor of intervention outcomes (symptom severity, symptom consequences, and symptom distress)?

(b) What are the active ingredients of the nurse-delivered WRITE Symptoms intervention?

To answer the fourth research question, two regression models were proposed. The first model seeks to understand how intervention fidelity influences study outcomes. Hierarchical multiple linear regression analysis is proposed using socio-demographic characteristics and the baseline symptom representation score as control variables, using the sum score of intervention fidelity as an independent variable of interest, and, using the symptom representation score at

twelve weeks post-baseline as a dependent variable. The second model explores which elements of the intervention are critical or active ingredients. A similar regression model is proposed. The variables to be controlled will be socio-demographic characteristics and the baseline symptom representation score. The intervention fidelity score of each of thirteen subscales of the WRITE Symptoms fidelity instrument will be independent variables of interest, and the symptom representations score at 12 weeks post-baseline will be a dependent variable.

Having addressed the four research questions, this study contributes to the advancement of intervention research for several reasons. First, the fidelity instrument was found to be a reliable tool for assessing intervention fidelity in the WRITE Symptoms intervention. Second, should the WRITE Symptoms intervention prove to be efficacious as hypothesized, each desired behavior addressed in the instrument will be useful in dissemination and translation of the intervention into clinical settings in the next step. Further, the instrument has the distinction of being the only web-based, psycho-educational fidelity tool available. While it is specific to the WRITE Symptoms intervention, it includes subsets of behaviors relevant to other RA interventions; web-based psycho-educational interventions; and, cancer symptom management interventions. Its application in other web-based psycho-educational and RA-based interventions is inevitable. Its use is assured given the likely increased use of web-based interactions between clinicians and their patients due to factors such as logistics.



## 4.0 RESULTS MANUSCRIPT: DEVELOPMENT AND TESTING OF THE WRITE SYMPTOMS FIDELITY INSTRUMENT

### 4.1 ABSTRACT

**Background:** Intervention fidelity refers to the degree to which a treatment or intervention is administered as intended. Assessing intervention fidelity is essential for evaluating internal validity of a clinical trial and making inferences regarding the efficacy of an intervention. WRITE Symptoms (A Written Representational Intervention To Ease Symptoms) is a web-based psycho-educational intervention, based on the Representational Approach (RA) to patient education. Its primary aim is to help women with recurrent ovarian cancer better manage their multiple symptoms. Although many intervention fidelity instruments have been developed for a range of clinical trials, none specifically address web-based symptom management interventions.

**Objective:** To develop and test the WRITE Symptoms fidelity instrument. **Methods:** This ancillary study was conducted in two phases including (1) the development of the fidelity instrument, and (2) psychometric evaluation of the instrument. Phase 1 began with a review of the fidelity literature and the underlying theory to guide item selection and scaling for the instrument. Several rounds of expert review, pilot testing, and item revision resulted in the preliminary instrument used in Phase 2. In Phase 2, we evaluated inter-rater reliability and two-week intra-rater reliability. Three independent raters rated intervention sessions using data

extracted from interventionist-participant message board postings from the first twenty (n=20) completed intervention sessions from an ongoing RCT. **Results:** The final instrument, comprised of 13 subscales with 54 items, has acceptable psychometric properties with a weighted Kappa of 0.47 to 1.00 and percentage of agreement (POA) of 85 to 100 for each item for inter-rater reliability, and weighted Kappa of 0.48 to 1.00 and POA of 85 to 100 for each item for intra-rater reliability. For inter-rater reliability, overall weighted Kappa statistics for each subscale were between 0.53 and 0.94. Overall weighted Kappa statistic for the instrument was 0.83. For intra-rater reliability, overall weighted Kappa statistics for each subscale were between 0.66 and 0.96. Overall weighted Kappa statistic for the instrument was 0.93. **Conclusions:** The WRITE Symptoms fidelity instrument is a valid and reliable measure of fidelity to the nurse-delivered WRITE Symptoms intervention. Implementing the instrument as part of a comprehensive fidelity monitoring plan will help maximize internal validity of the RCT. It can also be used to evaluate the impact of fidelity on intervention outcomes and to identify the active ingredients of the intervention. Finally, the instrument could be easily adapted to assess fidelity in other intervention studies that are based on the Representational Approach to patient education or other web-based symptom management studies.

## 4.2 INTRODUCTION

One of the most important aspects of an intervention study is to evaluate whether changes in the dependent variable(s) are caused by manipulation of the independent variable(s) (Gresham et al., 1993; Peterson et al., 1982; Shadish et al., 2002; Sidman, 1960; Stein, Sargent, & Rafaels, 2007). Considerable time and resources have been dedicated to generating operational definitions and

developing and testing the reliability and the validity of instrument that measure dependent variables and covariates in intervention studies. Unfortunately, comparable attention has rarely been given to operationalizing and measuring the actual intervention (the independent variable) (Gresham et al., 1993; Peterson et al., 1982). It is increasingly recognized, however, that if data to support the accurate operationalization and delivery of the independent variable are not reported, conclusions of a study are not defensible. To merely assume that an intervention was delivered as outlined in a method section or intervention manual is inadequate (Gresham et al., 1993).

Several guidelines exist to assist researchers in implementing, monitoring, and evaluating intervention fidelity – defined as the degree to which treatments or interventions have been delivered as intended (Bruckenthal & Broderick, 2007; Carroll et al., 2000; Carroll et al., 2007; Gresham et al., 1993; Moncher & Prinz, 1991; Peterson et al., 1982; Santacrose et al., 2004; Tucker & Blythe, 2008; Wilkinson, 2006, 2007). While these guidelines differ in whether they include participant responses as a part of fidelity, they are similar in focusing on explicating the key elements of the intervention and on training and monitoring of interventionists to ensure accurate delivery of those intervention elements.

As our fidelity conceptualization, in this study, focuses solely on delivery of the intervention elements by the interventionist, one such model, the technology model (Carroll et al., 2000; Santacrose et al., 2004; Waskow, 1984) was selected as a guideline for developing a plan for monitoring and evaluating intervention fidelity. The model has four components (1) study design, which includes the development of a comprehensive intervention manual (to ensure that the intervention is congruent with its underlying theory); (2) training (to ensure that the interventionists are qualified and consistently trained); (3) monitoring (to ensure the

intervention is delivered as intended); and, (4) including the fidelity scores in the analysis of treatment efficacy. This simple, comprehensive model which focuses on interventionist's behavior was ideal for guiding the development of a fidelity plan for our nurse-delivered intervention, **WRITE Symptoms (A Written Representational Intervention To Ease Symptoms)**.

WRITE Symptoms is a theory-guided, web-based intervention designed to improve symptom management for women with recurrent ovarian cancer. The intervention is delivered via an interactive computer module (self-directed WRITE Symptoms) or by nurses via secure Internet message boards (nurse-delivered WRITE Symptoms). WRITE Symptoms was developed based on the Representational Approach (RA) to patient education (Donovan et al., 2001; 2007). The 8-week intervention addresses symptom management by following the seven key elements of the RA: (1) representational assessment of symptoms; (2) exploring concerns, misconceptions, and gaps related symptom management; (3) creating conditions for conceptual change; (4) introducing evidence-based symptom management information; (5) summary; (6) goal setting and strategy selection; and (7) strategy review and revision. The intervention addresses up to three symptoms selected by the participant related to ovarian cancer and its treatment.

One of the innovative aspects of nurse-delivered WRITE Symptoms is that the intervention is exclusively delivered via asynchronous web-based message boards, allowing the nurse and participant to post messages at different times on a shared message board. Per protocol, the nurse responds back within the next business day. The nurse coaches the participant through the seven elements of the RA, developing individualized goals and strategies to help her learn the process of managing multiple symptoms. Details of the RA and WRITE Symptoms

study have been described elsewhere (Donovan et al., 2001; 2007; Dumrongpakapakorn et al., 2009).

The WRITE Symptoms Study is a three arm randomized controlled trial (RCT) designed to compare efficacy of nurse-delivered WRITE Symptoms to self-directed WRITE Symptoms to care-as-usual in improving symptom management for women with recurrent ovarian cancer (NIH NR010735; GOG0259; Donovan, PI) The primary goal of the WRITE Symptoms study is to determine if changes in symptom representations (symptom severity, consequences, and distress) are the result of a systematic manipulation of the independent variable (nurse-delivered WRITE Symptoms vs. self-directed WRITE Symptoms vs. care-as-usual). The nurse-delivered WRITE Symptoms intervention is highly individualized, flexible and dynamic. This increases the risk of inaccurate and inconsistent delivery of the intervention. Therefore, fidelity to the nurse-delivered WRITE Symptoms intervention needs to be included when testing the hypothesis that outcomes in participants who received the nurses-delivered intervention are superior to those who received the self-directed intervention or care-as-usual.

To ensure fidelity of the WRITE Symptoms intervention and to optimize validity of findings at the conclusion of the study, we developed the comprehensive plan for monitoring and evaluating intervention fidelity based on the technology model. One of the most important tools for implementing the plan is a valid and reliable fidelity instrument that captures the essential interventionist behaviors necessary to accurately deliver the WRITE Symptoms intervention. Therefore, the purposes of this study were to: (1) develop the WRITE Symptoms fidelity instrument and (2) evaluate its psychometric properties.

## **4.3 METHODS**

The development and evaluation of the WRITE Symptoms fidelity instrument was a multi-step process conducted in two phases. Phase 1 (instrument development) included item generation, item selection, item scaling, and preliminary item testing. Phase 2 (psychometric evaluation) included evaluation of inter-rater reliability and intra-rater reliability.

### **4.3.1 Phase 1: Development of the WRITE Symptoms fidelity instrument**

#### **4.3.1.1 Item generation**

Initial items were generated based on an extensive review of the fidelity literature, the RA theory, and elements of the WRITE Symptoms protocol. Following the process recommended by Calsyn (2000) and Waltz and colleagues (1993), two research members (HD and PD) worked to reach consensus about the types of behaviors thought to be essential for the successful delivery of the WRITE Symptoms intervention, including: (1) behaviors that were essential and unique to WRITE Symptoms and/or RA, (2) behaviors that were essential but not unique, (3) proscribed behaviors, and (4) asynchronous web-based behaviors (Table 2). Items that reflected behaviors essential and unique to WRITE Symptoms and/or RA or proscribed to WRITE Symptoms and/or RA were generated directly from the theoretically-guided elements of the WRITE Symptoms intervention and principles of effective symptom management. The remaining items were generated based on a broad review of the psycho-educational intervention and computer-based intervention literature. Items were discussed and revised until consensus was reached between the two research members. Then, other research team members (JK and nurse interventionists)

verified congruence between the intervention manual and the items. The resulting instrument was comprised of 72 items, grouped into 13 subscales (Table 2).

**Table 2 Scales identified based on theory underpinning the WRITE Symptoms study, fidelity literature, and categorized by type of behaviors**

Type of behaviors	Subscale	Goal
		To evaluate the extent to which the interventionist:
1.Unique and essential	1. <i>Representational assessment</i>	Encouraged participant to describe her symptom along the six dimensions of representations: identity, cause, timeline, consequences, cure or control, and emotion. The goal is to get a clear picture of the participant's understanding of the symptom and identify any concerns, misconceptions, or gaps in understanding.
	2. <i>Exploring concerns, misconceptions, gaps in knowledge</i>	Encouraged participant to think and talk about what experiences led to the development of any identified concerns, misconceptions, or gaps. The goal is to understand how any identified concerns, misconceptions, or gaps developed.
	3. <i>Creating conditions for conceptual change</i>	Helped the participant recognize limitations of her current representations -- i.e., ways in which concerns, misconceptions, or gaps may be contributing to inadequate symptom management.
	4. <i>Providing new information</i>	Provided new information (e.g. evidence-based recommendations for symptom management and statements to counter common concerns or misconception).
	5. <i>Setting goals &amp; strategies</i>	Worked with participant to develop goals related to improving the symptom and specific strategies for reaching those goals.
	6. <i>Summary</i>	Discussed benefits associated with acting on new information.
	7. <i>Strategy evaluation</i>	Discussed whether participant was able to implement strategies, what problems were encountered, any concerns participant has, how well strategies worked, and whether goal was reached.
	8. <i>Goal &amp; strategy revision</i>	Discussed whether participant want to continue using the same strategies to manage her symptom, and assisted the participant to revise goal and strategy if necessary.
	9. <i>Teaching the RA process</i>	Identified and reiterated steps in RA process, began turning over RA process to participant when working on symptom 2, and encouraged independent use of RA process with symptom 3.
2.Essential but not unique	10. <i>Therapeutic alliance</i>	Developed therapeutic alliance in addressing goals of better symptom management such as avoiding use of judgmental statements, and willingness to address emotional or difficult topics.
	11. <i>Consistent flexible application of protocol</i>	Demonstrated consistent, but flexible application of protocol such as being able to modify sequence and focus of the intervention while still completing the full RA for at least one symptom.
3.Proscibed	12. <i>Fidelity to scope of intervention</i>	Focused on symptom management, avoided prescriptive advice and recommendations that are not supported by evidence-based Symptom Care Guides.
4.Asynchronous web-based skills	13. <i>Asynchronous web-based skills</i>	Used effective web-based intervention behaviors such as: responding within 24 hours, using strategies to make text more reader friendly, matching tone, reading level, and number of questions/text appropriate to information provided by participant.



#### **4.3.1.2 Item selection: content validity and item clarification**

To establish item clarity and content validity, the initial instrument was reviewed by a panel of five experts in fidelity assessment and the RA. All experts were PhD-prepared (four nurses and one social worker). All were experienced in developing and evaluating representational interventions and had conducted intervention research that included fidelity evaluations. The experts focused on item clarity and how well the instrument identified behaviors unique and essential to the intervention as well as general behaviors essential and common to most psycho-educational interventions. Their feedback led to refinement of the fidelity instrument. For example, the subscale entitled “summary” which originally consisted of four items was revised and reduced to only two items (*1. When the nurse submits the symptom care plan, did the nurse provide a summary of the ways engaging in this systematic process (the Representational Approach) and trying new strategies can help participant get better control over symptoms?, and 2. Did the nurse orient the participant to the process of implementing and evaluating new strategies?*). At the completion of the expert review, the instrument was reduced to 62 items.

#### **4.3.1.3 Item Scaling**

In deciding on item scaling we considered Likert-type scales versus dichotomous responses. Compared to Likert scaling, dichotomous scaling is more likely to achieve greater inter-rater reliability (Waltz et al., 1993); however, it does not quantify the degree to which the required behavior was performed by the interventionist. Initially, we used a 5-point Likert-type format based on the Yale Adherence and Competence Scale (YACS) (Carroll et al., 2000). Although the 5-point Likert-type scale provides an advantage in capturing discrete levels of the behavior performed (Waltz et al., 1993), other researchers have reported that the response options of a 5-point Likert scale are difficult to operationalize which can lead to a large degree of subjectivity

in the ratings and lower inter-rater reliability (Waltz et al., 1993). Our preliminary pilot testing confirmed this weakness. We found it difficult to reach agreement using the 5-point Likert-type scale. Consequently, we adopted a 3-point Likert-type scale to make the items easier to rate, decrease subjective interpretation of individual items and possibly increase inter-rater reliability.

#### **4.3.1.4 Preliminary item testing**

We evaluated inter-rater reliability of the instrument on a sample of five mock interventions generated during interventionist training. Percentage of agreement (POA) between two raters (HD and PD) was calculated for individual items and the full instrument. The POA for the full instrument ranged from 82.69 to 94.23 across interventions. However, minor clarifications and refinements were necessary. Nine items were deleted due to redundancy and/or low reliability; others were modified to clarify language; two items were split into two questions, one additional item was removed later during the rater training process due to redundancy. See Appendix A for the final 54-item fidelity instrument.

### **4.3.2 Phase 2: Inter-rater reliability and intra-rater reliability**

#### **4.3.2.1 Design and Sample**

During this phase, we extracted all posts from the first twenty ( $N = 20$ ) completed intervention sessions from the nurse-delivered intervention arm of the WRITE Symptoms study. The sample size justification was calculated based on recommendations from previous studies which indicate that the minimum sample size required for the valid application of weighted kappa can be estimated by the simple formula  $2k^2$  (where  $k$  is a number of categories of classification)

(Cicchetti, 1981; Cicchetti & Fleiss, 1977). In this study, this formula produces a sample size equal 18 (when  $k = 3$  [“0” = not at all; “1” = some; and, “2” = completely]).

To be considered a “completed” intervention session, the participant and a nurse interventionist pair had to have worked through the 7 elements of the RA for at least two symptoms. For sessions in which all three symptoms were addressed, text from the first symptom was evaluated, and text from either the second or third symptom was randomly selected for evaluation. The first symptom was always evaluated because the protocol for the first symptom requires the nurse to explicitly lead the patient through each element of the RA process. The second or third symptom was evaluated because it allowed the rater to assess whether the interventionist successfully enabled the participant to use the RA process in a self-guided fashion when discussing subsequent symptoms.

#### **4.3.2.2 Instrument: WRITE Symptoms fidelity instrument**

The full instrument is provided in Appendix A. The instrument includes 54 items in 13 subscales. Raters evaluate the extent to which an interventionist performed each target behavior. Each item is rated on a scale of “0” = not at all; “1” = some; and, “2” = completely.

#### **4.3.2.3 Rater selection and training**

Proper training of the raters is essential to guaranteeing reliable utilization of the instrument. Scoring of intervention sessions is a complex task requiring expertise comparable to that of the study interventionist so it is essential that raters have knowledge and experience related to the intervention (Carroll et al., 2000; Moras & Hill, 1991). For this study, the raters included author PD and two other doctoral students who were knowledgeable about the RA, the WRITE

Symptoms intervention, ovarian cancer, and symptom management. All raters underwent specific training, including didactic lectures on the theoretical underpinnings and specific elements of the intervention, and independent reading and group discussion of the RA, the WRITE Symptoms study protocol, and the intervention manual. Every rater was provided a copy of the fidelity instrument, the process for rating intervention sessions, and examples of intervention sessions and scores rated by experienced raters (HD and PD) as exemplars. Training consisted of three 2-hour practice sessions. During each session, the raters rated a mock intervention session, discussed the intervention, and requested additional clarification from HD when discrepancies in scorings remained after discussion. Once all raters felt comfortable with the instrument and scoring procedures, they were asked to score one additional intervention session. Scores were compared with those from HD and PD and a POA of 80 was set as the benchmark, where  $POA = (\text{Total number of items in agreement} / \text{Total number of items in the instrument [54]}) * 100$ . Both raters achieved the benchmark ( $POA = 96.30 - 98.15$ ). Discrepancies were found in the scoring of three items. More instruction and practice were provided for calibration.

#### **4.3.2.4 Procedure**

Transcripts of the intervention sessions were evaluated. The entire set of interactions on the nurse-participant message board was extracted from the WRITE Symptoms database. All posts related to two symptoms were selected for the fidelity analysis. In order to avoid the risks of rating bias specific to knowing who the interventionist is (e.g. nurse interventionist names are included in messages; all four nurse interventionists are known to the raters; and messages often include personal anecdotes), several steps were taken. The participant's name, the nurse

interventionist's name, and any relevant information that could unblind the rater to the identity of the interventionist (e.g. where the interventionist lives, reference to their family) were de-identified, and each intervention session was given a unique ID.

To evaluate *inter-rater reliability* of the fidelity instrument, the intervention sessions were rated independently by two raters (KW and PD or TH and PD). Raters were instructed to read each intervention session in its entirety prior to rating specific items. Raters then scored each item on the basis of how extensively the interventionist performed the target behaviors ("0" = not at all; "1" = some; and, "2" = completely). For *intra-rater reliability*, the same raters rated their same set of twenty messages a second time, two weeks after their first rating. A two-week time period is considered sufficient to prevent carry-over effects (Bailar & Mosteller; 1992).

#### **4.3.2.5 Data analysis and interpretation**

A data set consisting of fidelity scores for each item from each independent rater was created using excel 2007. POA and weighted Kappa statistic estimates were calculated for each item. The POA was calculated using this formula: (Total number of interventions in agreement/ Total number of interventions [20]) \* 100. The weighted Kappa statistic estimates were calculated to examine inter- and intra-rater reliability using SAS statistical software (SAS Institute, Cary, NC, U.S.A.) (FREQ procedure, option AGREE). We interpreted the level of rater agreement by using the five-level categorization recommended by Landis and Koch (1977): 'slight agreement' (Kappa values =0.0-0.2), 'fair agreement' (0.21–0.4), 'moderate agreement' (0.41–0.6), 'substantial agreement' (0.61– 0.8) and 'almost perfect agreement' (0.81–1). There has been no real discussion regarding what is an acceptable POA in the literature (Wickersham et al., in press); therefore, we chose 80% agreement as our benchmark. Consideration was given to items

with the Kappa statistics less than 0.61 for further revisions. In the event a low Kappa statistic occurred with low POA (less than 80), the items were revised for clarification by having all the raters discuss the specific items and reach consensus on changes to be made. The revised items were rated again by the same group of raters (PD and TH or PD and KW). Kappa statistics and POA were recalculated.

#### **4.4 RESULTS**

Table 3 provides the overall values of the inter-rater and intra-rater reliability of the WRITE Symptoms fidelity instrument, expressed as weighted Kappa statistics, were high. All Kappa statistics ranged from 0.47 to 1.00 with POAs equal to 75 or higher. For inter-rater reliability, overall weighted Kappa statistics for each subscale were between 0.53 and 0.94. Overall weighted Kappa statistic for the instrument was 0.83. Table 4 provides overall instrument reliability information. For intra-rater reliability, overall weighted Kappa statistics for each subscale were between 0.66 and 0.96. Overall weighted Kappa statistic for the instrument was 0.93.

Four items (items 8, 33, 42, and 43) had Kappa statistics equal to or less than 0.60 and POA equal to or less than 80. HD, the PI of the Write Symptoms study and co-developer of the fidelity instrument, acted as a reviewer to identify potential issues in scoring rules and/or training. Through this process, we discovered the coding rules for these items were unclear and in two cases were different than the original intent of the items. Thus, the coding rules were revised and the new rules were discussed with all raters to ensure the new coding rules were accurate and easy to follow for future raters. Subsequently, the same group of raters (PD and TH

or PD and KW) rated the four items again. A recalculation of the Kappa statistics and POA was done and the final results reported (Table 3). All items attained benchmark scores based on Kappa statistics and POA.

We also identified 20 items with no variability (those with  $K_w$  equals \* in Table 3). This occurred as a result of all raters scoring the item as a “2” for every intervention session.

**Table 3 Inter-rater reliability and intra-rater reliability**

Item	Inter-rater reliability				Intra-rater reliability	
	POA	K <sub>w</sub>	Revised POA	Revised K <sub>w</sub>	POA	K <sub>w</sub>
1 Identity	100.00	*			100.00	*
2 Cause	100.00	1.00			97.50	0.66
3 Timeline	100.00	*			100.00	*
4 Consequences	100.00	*			100.00	*
5 Cure/control	100.00	*			100.00	*
6 Emotion	95.00	0.79			100.00	1.00
7 Exploring concerns	85.00	0.65			97.50	0.94
8 Miss opportunities to explore concerns	75.00	0.67	85.00	0.72	85.00	0.68
9 Symptoms as “controllable”	100.00	1.00			100.00	*
10 Concerns and ineffective symptom management	95.00	0.93			97.50	0.96
11 Alternative ways of thinking about concerns	95.00	0.89			97.50	0.94
12 Encourage the use of new strategies	100.00	*			100.00	*
13 Refer to the symptom care guide (SCG)	100.00	*			100.00	*
14 Give an overview of the SCG	100.00	*			100.00	*
15 Discuss information from the SCG in more detail	100.00	*			100.00	*
16 Discuss the importance of talking with HCT	90.00	0.82			95.00	0.91
17 Work to set a SMART goal	95.00	0.64			100.00	1.00
18 Ask to identify a strategy	95.00	0.64			97.50	0.79
19 Seek input from the participant to select strategies	100.00	*			100.00	*
20 Provide guidance in breaking down strategies	85.00	0.58			97.50	0.93
21 Validate goals and strategies	100.00	*			100.00	*
22 Provide a summary of the RA	90.00	0.84			97.50	0.96
23 Orient the process of implementing & evaluating strategies	95.00	0.78			100.00	1.00
24 Assess the implementation of strategies	100.00	1.00			100.00	1.00
25 Assess barriers about use of strategies	100.00	1.00			100.00	1.00
26 Assess the effectiveness of the strategies	100.00	1.00			100.00	1.00
27 Ask if the participant want to modify goals and strategies	95.00	0.91			100.00	1.00
28 Strategy discussion	100.00	1.00			100.00	1.00
29 Emphasize the need for strategy adjustments	95.00	0.95			95.00	0.92
30 How the intervention works	95.00	0.64			95.00	0.48
31 A tentative agenda	100.00	*			100.00	*
32 Teach the RA	95.00	0.64			100.00	1.00
33 Encourage the use of the RA	80.00	0.43	95.00	0.47	95.00	0.84
34 Demonstrate individualization	100.00	1.00			95.00	0.78
35 Flexible in addressing questions/ problems	100.00	1.00			100.00	1.00
36 Break down complex information	100.00	*			100.00	*
37 Use probes	90.00	0.65			97.50	0.94
38 Cooperation and working together	100.00	*			100.00	*
39 Avoid emotional/difficult topics	100.00	*			100.00	*
40 Non-judgmental manner	100.00	*			100.00	*
41 Ask open-ended questions	90.00	0.44			100.00	1.00
42 Invite to ask questions	75.00	0.58	100.00	1.00	97.50	0.96
43 Check if understanding was accurate	80.00	0.60	100.00	1.00	97.50	0.95
44 Summarizing the main points	95.00	0.88			100.00	1.00
45 Avoid giving advice on cancer treatment	100.00	*			100.00	*
46 Avoid giving prescriptive advice	90.00	0.47			97.50	0.85
47 Not recommend strategies not included in algorithms/SCGs	100.00	*			100.00	*
48 Ask safety questions	100.00	1.00			100.00	1.00
49 Tell the participant to contact HCT if new symptoms arise	80.00	0.69			92.50	0.87
50 Respond within 24 hours	95.00	0.86			97.50	0.93
51 Make text reader-friendly	100.00	*			100.00	*
52 Offer to break up information	85.00	0.69			85.00	0.77
53 The numbers of questions asked appropriate	100.00	*			100.00	*
54 Match tone, reading level, use of humor	100.00	*			100.00	*

K<sub>w</sub> = Weighted Kappa; POA = Percentage of Agreement

\* = Kappa cannot be calculated. POA equals 100 and there is no variability in scoring for that item (e.g. rater A and rater B scored “2” for that item in every intervention session).



**Table 4 Overall instrument Kappa and Subscale Kappa**

<b>Subscale</b>	<b>Inter-rater reliability (K<sub>w</sub>)</b>	<b>Intra-rater reliability (K<sub>w</sub>)</b>
1 Representational Assessment	0.79	0.66
2 Exploring Concerns	0.66	0.90
3 Creating conditions for Change	0.92	0.96
4 Provides New Information	*	0.91
5 Setting Goals & Strategies	0.61	0.91
6 Summary	0.81	0.96
7 Symptom follow up/Goal Strategy Review	*	*
8 Goal & Strategy Revision	0.94	0.92
9 Teaching the RA Process	0.53	0.79
10 Consistent flexible application of protocol	0.65	0.92
11 Therapeutic alliance	0.71	0.95
12 Fidelity to scope of intervention	0.61	0.86
13 Asynchronous web-based skills	0.77	0.86
Overall instrument	0.83	0.93

K<sub>w</sub> = Weighted Kappa

\* = Kappa cannot be calculated because all standard errors are zero

## **4.5 DISCUSSION**

According to Landis and Koch's criteria (Landis & Koch, 1977), the overall values of Kappa statistics qualified as substantial or almost perfect. Therefore, the fidelity instrument is a reliable tool for assessing intervention fidelity in the WRITE Symptoms intervention as demonstrated in this study.

One notable finding of this study was that 20 of the items had no variability. This finding led the research team to take a deeper look into the use and experiences with the message posting process. Throughout the WRITE Symptoms intervention a nurse uses one of three general types

of posts: automated, standardized, and individualized. The first post of the intervention is automatically generated by the computer system when a patient is assigned to the nurse-delivered intervention and initiates the representational assessment. This post does not require any “action” on the part of the interventionist. The second type of post is standardized and does not require high-level skills of the interventionist. An example of this type of post is a piece of information cut from the intervention manual and pasted into a post. While such a post does not require a customized response, it is still necessary for the interventionist to (1) decide to use it, (2) use it accurately, and (3) use it at appropriate time. For this type of post, the rater monitors whether or not the post occurs in response to the participant’s comments or inquiries. The third type of post requires individualization and a high-level of skill. An example of this type of post occurs when the interventionist reads a symptom or complaint described by the participant. The interventionist then specifically addresses the issue with accurate information and/or direction to the Symptom Care Guide, etc. in a tone reflecting the participant’s. In looking to explain low variability of items, we suspected that it might be easier for interventionists to fully adhere to, and require less judgment on the part of raters to score, the standardized posts. This could lead to lower variability among standardized posts. However, that was not the case: 4 of the low variability items (1, 3, 4, and 5) were of the automated type, 4 items (12, 13, 21, and 31) were of the standardized type, and 12 items (14, 15, 19, 36, 38, 39, 40, 45, 47, 51, 53, and 54) were of the individualized type. This suggests that other factors are at play.

Perhaps these 20 items are “easier” to carry out as an interventionist than other items, regardless of whether they require individualization. If these items are, indeed, easy to carry out, researchers could choose to not include them in certain aspects of the fidelity monitoring plan. For example, it would still be important to include their assessment in the real-time selection of interventions used to monitor and re-train interventionists and to minimize intervention drift.

However, when evaluating the effect of intervention fidelity on study outcomes, all interventions must be coded. This is an extremely time consuming task for raters and for this purpose, a researcher may want to select a parsimonious set of questions that capture the greatest amount of variability in the tool. In this situation, one could argue for eliminating these 20 low variability items.

The WRITE Symptoms fidelity instrument also has the potential to be used in analyses to identify the critical components (or active ingredients) of the WRITE Symptoms intervention. In this type of analysis, removing the low variability items would not be recommended as each of these items represents a critical aspect of the intervention. Future research should explore how best to use the fidelity tool in analyses of critical ingredients of the WRITE Symptoms intervention, such as whether items or subscales should be equally or differentially weighted.

One limitation that must be noted is the difficulty in operationalizing a “1” for certain items. This limitation was initially recognized with the 4 items that had poor inter-rater reliability during Phase 2 of this study. This issue was resolved for those four items, but it could be argued that this problem still exists with other items in which there are not specific rules for coding a “1” (e.g. items 1-6). This weakness should be addressed in future implementations and testing of the instrument.

It should also be noted that the interventionists in this study achieved exceptionally high fidelity ratings for this complex intervention, receiving the highest rating (2) on a majority of items for each intervention. This likely occurred for several reasons. First, we had highly trained interventionists involved in the development of the Symptom Care Guides, intervention manual, and fidelity instrument. While this demonstrates the benefit of including interventionists in the development and implementation of a fidelity monitoring plan, these interventionists are likely to

represent “optimally” trained interventionists. It is unlikely that all future interventionists will have the opportunity for such extensive training. Therefore, it is unclear whether raters would achieve such high inter-rater reliability in situations where fidelity to the intervention is more variable. For example, the difficulties raters noted in consistently operationalizing a “1” in this study may be heightened with posts from less-skilled interventionists. We identified a similar potential limitation when looking into the number of symptoms selected by the participants in this study. From the list of 28 potential symptoms only 9 symptoms were selected to work on by participants in this study (fatigue [n=6]; constipation [n=4]; peripheral neuropathy [n=2]; abdominal bloating [n=2]; weight gain [n=2]; anxiety [n=1]; pain [n=1]; diarrhea [n=1]; and hot flashes [n=1]). This issue raises a question as to whether reliability of the instrument or intervention fidelity would be different for different or less prevalent symptoms. Perhaps interventionists can achieve higher fidelity for more frequently addressed symptoms than for less frequently addressed symptoms. Again, it is possible that higher variability in fidelity could lead to lower inter-rater reliability for less frequently addressed symptoms. Future research to address whether or not the inter-rater reliability scores for skilled versus unskilled nurses and for frequent symptoms versus infrequent symptoms should be considered.

Finally, while the instrument was developed based on an extensive review of the fidelity literature, RA theory, and elements of the WRITE Symptoms intervention to ensure validity, it must be acknowledged that a comprehensive evaluation of construct validity was not included in this study. As a result, it is possible that although the instrument is reliable, it may not be a valid assessment of fidelity. Further validation studies are warranted.

Despite potential limitations, we believe that the WRITE Symptoms fidelity instrument is a useful tool for monitoring and evaluating correspondence between the interventionists’

behaviors and the intervention protocol. Looking forward, in the event the intervention outcomes are as favorable as hypothesized, dissemination and translation of the intervention into clinical settings will be the next step. The instrument will help to ensure accurate dissemination of the intervention and increase the likelihood of successful adoption by clinicians.

Furthermore, although the instrument is specific to the WRITE Symptoms intervention, it includes subsets of behaviors relevant to other interventions based on the RA; web-based psycho-educational interventions; and, cancer symptom management interventions. Its features and benefits are flexible and noteworthy, but first and foremost, it is the only web-based, psycho-educational fidelity instrument available. Given the increasing use of web-based interventions, this instrument will evolve as more researchers and then, optimally clinicians, put it into use.

In summary, this narrative of the development of a comprehensive instrument to ensure fidelity in a complex RCT demonstrates how researchers may apply the process in their own studies. Furthermore, the WRITE Symptoms fidelity instrument can help other researchers and clinicians to operationalize the key elements of the WRITE Symptoms intervention or other similar RA interventions. Ultimately, if the instrument promotes intervention fidelity, improves internal validity of the trials in which it is used, enables the identification of the active ingredients of the intervention, and increases the likelihood of successful adoption by clinicians, then it will be an important tool for advancing the science of intervention research.

## **5.0 RESULTS: TRAINING MANUAL**

The purpose of this chapter is to address the third specific aim of this dissertation “to establish a fidelity monitoring plan for the nurse-delivered WRITE Symptoms intervention”. To accomplish the aim, this manual was developed to address how to: (1) use the instrument to monitor fidelity of the nurse-delivered WRITE Symptoms intervention, and, (2) train raters to use the instrument.

As a result of the development and refinement of the WRITE Symptoms fidelity instrument, the final fidelity instrument consists of 54 items. It includes 13 subscales of behaviors necessary for conducting the intervention as identified based on theory underpinning the WRITE Symptoms study and fidelity literature. The instrument acknowledges four types of behaviors deemed essential for the successful delivery of the WRITE Symptoms intervention: (1) essential and unique (behaviors that are essential to the WRITE Symptoms interventions but not be expected to be found in other types of interventions); (2) essential but not unique (behaviors that are essential to the WRITE Symptoms interventions but not unique to them); (3) proscribed (behaviors that should not occur in any of the WRITE Symptoms intervention sessions); and (4) necessary for asynchronous web-based interventions (behaviors considered essential in conducting asynchronous web-based interventions. The instrument was designed to be a Likert scale instrument with response options on a 3-point scale. A rater is asked to evaluate the extent to which an interventionist performs target behaviors on a scale of “0” = not at all; “1” = some; and, “2” = completely. The 54 items are demonstrated in the following section.

## **5.1 HOW TO USE THE INSTRUMENT TO MONITOR FIDELITY OF THE NURSE- DELIVERED WRITE SYMPTOMS INTERVENTION**

As a detailed step-by-step guideline to direct how the WRITE Symptoms intervention should be delivered to a participant, the fidelity instrument helps all individuals involved in the process to develop a solid comprehension of the intervention such as what behaviors are expected, what behaviors are prohibited, and the rating criteria for each target behavior. The fidelity instrument serves as a means of communicating to those working with the WRITE Symptoms intervention, including researchers, nurse interventionists, and raters. The WRITE Symptoms fidelity instrument is used to promote intervention fidelity in a variety of ways, as described in the following sections.

### **5.1.1 Use of instrument in interventionist training**

A key area of treatment fidelity is assessing and improving interventionist training to ensure they are satisfactorily prepared to deliver the intervention to study participants. Each interventionist brings a range of skills and experiences to a study which could affect the manner in which the intervention is delivered (Radziewicz et al., 2009). Therefore, to ensure the interventionist is trained properly to work within the WRITE Symptoms study format, an interventionist must receive comprehensive training, which includes:

### **5.1.1.1 Initial training to be qualified as an interventionist**

1. Directed readings:
  - a. Representational approach (RA) to patient education (Donovan & Ward, 2001; Donovan et al., 2007)
  - b. WRITE Symptoms study protocol
  - c. WRITE Symptoms study intervention manual
2. A two-day nurse interventionist training involving:
  - a. Presentation of the RA and the WRITE Symptoms study protocol by the Primary Investigator (PI),
  - b. PI and raters discussion of the RA and the WRITE Symptoms study protocol
  - c. Education about ovarian cancer, symptom management, and therapeutic communication
3. Practice interventions under the guidance of the PI, participant coordinator, and experienced nurse interventionists using intervention manuals, messages generated in the pilot study, and role-playing as both participant and nurse interventionist.
  - a. At the beginning of the practice session series, one-on-one training occurs between an experienced nurse interventionist and the trainee, supervised by the PI (who developed the intervention.) This is recommended because it provides in-depth understanding of each element of the intervention.
  - b. The fidelity instrument will be used to evaluate whether or not the interventionists performed target behaviors as planned. After finishing each practice session, the fidelity instrument will be reviewed by the PI to assist the interventionists in developing their proficiency in intervention delivery. While there is no criteria for



determining minimum trainee competency levels, it is recommended the cut off should be set high during training (e.g. completely performed at least 95 percent of the desired behaviors identified in the fidelity instrument), as decline or drifting of skills may be common after training. The evaluation and feedback will be provided to the interventionists at weekly team meetings, allowing the PI and experienced team members to provide further guidance with challenging aspects of intervention implementation. If interventionists do not reach the cut off, supplement training sessions are recommended until the interventionists reach the criteria for determining minimum trainee competency levels.

#### **5.1.1.2 Ongoing training**

To prevent waning or drift of interventionist behaviors over the course of the study, two processes are recommended.

##### ***Monthly evaluation***

Every month, a study manager will randomly select one intervention session (from each interventionist) and assign a trained rater to evaluate interventionist behavior using the WRITE Symptoms fidelity instrument. All items will be scored and results will be reported to either the PI or an assigned person. Feedback will be provided at the next weekly team meeting. If a major violation (such as the nurse recommended specific cancer treatment) is revealed, it will be addressed immediately with the PI. The violation and its resolution will be documented on a meeting report.

### ***Refresher training***

Twice a year for the duration of the study, or as determined by the PI, refresher training which includes discussion of the RA and Research protocol will be provided by PI.

#### **5.1.2 Self-monitoring and assessment of the WRITE Symptoms intervention delivery as part of the initial and ongoing training**

Interventionists will be instructed to use the fidelity tools to assess their own progress regarding implementation. After the initial training is complete, self-assessment will reveal the interventionist's comprehension and ability to implement the interventions thus providing an indicator of likely performance of intervention behaviors. Since the instrument indicates what behaviors are expected/ prohibited, the self-assessment process will assist the interventionist in identifying areas for improvement. In addition, repeated self-assessments will help the interventionist determine whether or not the targeted improvement strategies have resulted in change, as well as where to focus next in one's continued improvement efforts. This self-monitoring and assessment is proposed to remind interventionists about essential elements of the WRITE Symptoms to be delivered. It also acts as a mechanism to cue interventionists to implement the intervention with fidelity. This self-reported data should be used only as a supplement to enhance intervention fidelity. The intent is to encourage interventionists to check that they performed the desired behaviors and to gauge how well they did with the goal of continuity if doing well or to self-direct to do better. Interventionists should be instructed to randomly check at least two posts a month (or as determined by each study team).

### **5.1.3 Real-time (daily) monitoring and feedback at weekly meeting**

To monitor major protocol deviations or omissions, one research team member is assigned to read only the new messages posted on the message board daily and will use the fidelity instrument to gather information regarding how interventionists deliver the intervention. The reader will be looking for major deviations and not rating each item but instead ensuring the prescribed behaviors occur with the relevant posts. Conversely, deviated behaviors observed which are not desired will be noted and particular emphasis will be placed on proscribed behaviors, or, major violations. Then, the information will be shared with the WRITE Symptoms study PI. Any identified non-conformance to the study protocol will be brought by the study PI to weekly meetings for discussion and problem-solving with the interventionists and other research team members. If a major violation to the study protocol is detected, the study chair will meet with the interventionist as soon as possible for problem-solving.

### **5.1.4 Formal fidelity assessment**

Formal intervention fidelity assessment should be conducted by a well-trained rater to assess the fidelity score of an intervention session. All intervention sessions are reviewed and all fidelity items are scored. Participant and interventionist identities must be blinded. It is imperative that a trained approach to rating be used to assess the extent to which the interventionist performed target behaviors to ensure, as much as possible, consistency of rating. Following this, the fidelity score should be used as one of the independent variables of the study to examine the relationship between the intervention fidelity of the study and the study outcomes (see the Analytic Plan section for details.) The data analysis using fidelity scores obtained from using the fidelity

instrument to monitor the interventionists' behaviors will provide the WRITE Symptoms research team an opportunity to refine training and processes and act as a form of quality assurance for the study.

## **5.2 HOW TO TRAIN A RATER TO USE THE INSTRUMENT**

### **5.2.1 Who are the raters?**

A qualified rater must have a master's degree or be enrolled in a graduate program in nursing or a health-related field; be knowledgeable about the RA; the WRITE Symptoms intervention; and, ovarian cancer and symptom management.

### **5.2.2 Standard training for raters**

All raters are required to undergo specific training, which includes:

1. Didactic lectures by the PI on the theoretical underpinnings and specific elements of the WRITE Symptoms intervention.
2. Independent reading and group discussion of the RA (Donovan & Ward, 2001; Donovan et al., 2007), the WRITE Symptoms study, the intervention manual, and the training manual.
3. Practice sessions:
  - a. A trainee will be given an example of an intervention session and fidelity scores rated by experienced raters as examples of the typical way of determining the score. This will be done to familiarize the new rater with use of the instrument.

- b. Then, during three 2-hour practice sessions, the trainee will be given three selected intervention sessions (previously rated by an experienced rater), one at a time, and asked to rate the intervention using the fidelity tool. The trainer will review the ratings assigned by the trainee to determine which are correct or incorrect and discuss them accordingly.
- c. Once the trainer determines the trainee is sufficiently familiar with the instrument and scoring procedures, the trainee will be asked to score one additional intervention session. Scores will be compared with those from the experienced rater(s); if discrepancies are found, more instruction and practice will be required until the trainer and trainee reach eighty percent (80%) percentage of agreement (POA), or concurrence.

### **5.2.3 How will fidelity be assessed?**

Items will be reviewed and scored on the basis of how extensively the interventionist performs the target behaviors (“0” = not at all; “1” = some; and, “2” = completely).

## **6.0 RESULTS: ANALYTIC PLAN**

This chapter addresses the fourth aim “to propose an analytic plan to understand the influence of fidelity on the intervention outcomes”. As introduced in the first chapter entitled “introduction”, the analytic plan seeks to answer two research questions:

1. Is intervention fidelity a predictor of the intervention outcomes (symptom severity, symptom consequences, and symptom distress)?
2. What are the active ingredients of the nurse-delivered WRITE Symptoms intervention?

### **6.1 SPECIFIC AIMS**

With the purpose of understanding the influence of intervention fidelity on the intervention outcomes, and identifying the active ingredients of the nurse-delivered WRITE Symptoms intervention, this analytic plan addresses two specific aims:

1. Examine the relationship of the *intervention fidelity score* and the symptom representations (symptom severity, symptom consequences, and symptom-related distress), after controlling for baseline symptom representations and socio-demographic characteristics.
2. Examine the relationship between *each of the independent variables of interest (intervention fidelity score of each of the thirteen subscales of the WRITE Symptoms fidelity instrument)*

and the symptom representations (symptom severity, symptom consequences, and symptom-related distress), after controlling for baseline symptom representations and socio-demographic characteristics.

## **6.2 OVERVIEW OF RESEARCH DESIGN**

This is a proposed plan for a secondary analysis of data collected from a parent study conducted by Dr. Heidi Donovan: WRITE Symptoms study. The WRITE Symptoms study is a three-arm RCT currently being conducted to compare the efficacy of the two different web-based delivery systems (nurse-delivered via private web-based message boards versus self-directed using a web-based computer module) versus usual care in a sample of 480 women with recurrent ovarian cancer recruited from Gynecologic Oncology Group sites across the United States (NIH NR010735). The primary variables examined in the WRITE Symptoms study include women's symptom representations related to ovarian cancer and its treatment (symptom severity, symptom consequences, and symptom related distress). Details of the parent study were given in the "A Written Representational Intervention to Ease Symptoms" section of Chapter 1. However, in this present study, only data collected from 160 participants in the nurse-delivered WRITE Symptoms will be analyzed (N=160).



## **6.3 VARIABLES**

### **6.3.1 Independent variables**

Independent variables of interest consist of:

1. Socio-demographic characteristics are included as independent variables of this study because they are identified as important covariates from preliminary analysis defined for primary aim of the parent study.
2. Symptom representations at *baseline* (Three subscales of the Symptom Representation Questionnaire [identity, consequences, and emotional representation] will be used to represent the symptom representations [symptom severity, symptom consequences, and symptom-related distress] for this study.)
3. Thirteen intervention fidelity scores from thirteen subscales of the WRITE Symptoms fidelity instrument
4. Sum score of intervention fidelity

### **6.3.2 Dependent variable**

The dependent variable is symptom representations at *12 weeks* post-baseline.

## **6.4 MEASURES**

### **6.4.1 Socio-demographic characteristics**

Data were collected at baseline assessment using a Center for Research in Chronic Disorders Socio-Demographic survey. Socio-demographic characteristics in this study include age, ethnicity, and education.

### **6.4.2 Symptom representations**

Data are collected (at baseline assessment as an independent variable; and 12-week post-baseline assessment as a dependent variable) using the three subscales of the Symptom Representation Questionnaire (identity, consequences, and emotional representation). Participants are asked to select three symptoms they want to work on managing the symptoms (three symptoms they “noticed most” in the past week). The participants also are asked to complete the three subscales of the Symptom Representation Questionnaire for each of those 3 symptoms. The Symptom Representation Questionnaire was adapted from the Illness Perception Questionnaire. In a large sample of women with ovarian cancer (N= 713), the questionnaire demonstrated good psychometric properties with its subscales had internal consistency ( $\alpha$ ) ranges from 0.63–0.88 (Donovan, Ward, Sherwood, & Serlin, 2008).

*Identity scale* consists of 28 symptoms associated with ovarian cancer or its treatment. Participants are asked to answer concerning how severe each symptom was (Response options range from 0 [did not have] to 10 [as bad as I can imagine]) at its worst in the past week. Identity of symptom will be operationalized as the mean score for the three selected symptoms.

*Consequences of symptoms* are used to measure the degree to which each symptom affects the participant's life. The participants are asked to respond to three questions for each selected symptom with response options range from 0 (strongly disagree) to 4 (strongly agree). Consequences of symptoms will be operationalized as a single mean subscale score.

*Emotional Representation subscale* is used to measure the degree to which each symptom is intrusive, worrisome, and distressful. The participants are asked to respond to three questions with response options range from 0 (strongly disagree) to 4 (strongly agree). Similar to the consequences of symptoms subscale, emotional representation will be operationalized as a single mean subscale score.

Based on primary aim of the parent study, a composite score of symptom identity, consequences of symptom, and symptom-related distress for the three selected symptoms will be used to represent the dependent variable (symptom representations) of this analytic study.

### **6.4.3 Intervention fidelity scores**

The fidelity scores will be measured using the WRITE Symptoms fidelity instrument. The WRITE Symptoms fidelity instrument includes 54 items in 13 subscales. The instrument addresses four types of behaviors including (1) essential and unique (behaviors essential to the representational approach but not expected to be found in other approaches), (2) essential but not unique (behaviors essential to the WRITE Symptoms intervention but could be found as common factors in other interventions), (3) proscribed behaviors (behaviors that should not occur in any of the WRITE Symptoms interventions), and (4) behaviors necessary for asynchronous web-based interventions. Based on results presented in the manuscript chapter, the

WRITE Symptoms demonstrates good psychometric properties with a weighted Kappa range from 0.47 to 1.00 and POA range from 85 to 100 for each individual item for inter-rater reliability, and weighted Kappa range from 0.48 to 1.00 and POA range from 85 to 100 for each individual item for intra-rater reliability. The WRITE Symptoms fidelity instrument which will be used to monitor interventionist's behaviors by having a rater scores how extensively the interventionist performed target behaviors. The rater evaluates the extent to which an interventionist performs target behaviors for each item on a scale of "0" = not at all; "1" = some; and, "2" = completely.

*Thirteen intervention fidelity scores of each subscale of the WRITE Symptoms fidelity instrument:* A summed score for each subscale will be calculated to represent the scores for the items of each subscale. The possible range of the scores is 0 to 14.

*Sum score of the intervention fidelity score of the WRITE Symptoms fidelity instrument:* Mean scores from each subscale will be summed to create a single fidelity score (the four items with no variability (items 12, 13, 21, and 31) could be dropped before calculating the score). The possible range of the scores is 0 to 26.

## **6.5 DESCRIPTIVE STATISTICS**

All data will be analyzed with PASW Statistics 18.0 (SPSS, Inc., 2009, Chicago, IL,) for Windows. For all continuous variables with either ratio or interval levels of measurement (age, SRQ scores, and fidelity scores), mean and standard deviation (SD) will be used to describe

these variables, if the distribution of the variable is normal. If any of their distributions are not normal, median and inter-quartile range (IQR) will be used. For all categorical variables with either nominal or ordinal levels of measurement, frequency counts and percentages will be used to describe these variables. Mode will be used to describe central tendency of the nominal variables. For ordinal variables, central tendency will be described by median. Dispersion will be illustrated using range, minimum, maximum, and inter-quartile range (IQR) based on the variable's level of measurement and data distribution.

## **6.6 DATA SCREENING PROCEDURES**

Preliminary analyses will be conducted to examine data accuracy. Graphical representations of all the variables including range checking and contingency checking will be used for examining descriptive statistics. To explore univariate outliers, frequency of the variables will be used to examine imbalanced splits among levels of each category for categorical variables. For continuous variables, histograms, box plots, normality probability plots, and detrended normal probability plots will be performed to detect possible outliers. To explore multivariate outliers, bivariate scatter plots between each pair of variables will be performed for the set of dependent and independent variables of interest. If outliers are identified, regression analyses with and without outliers will be performed to evaluate whether the outliers are influential. The missing data analyses will be conducted to describe amount and pattern of missing data including where the missing values are located, how extensive they are, whether they are randomly missing, etc. Imputations of missing value might be considered to provide more accurate results.

In addition, assumptions for multiple linear regression, the primary analysis procedure to be applied when answering research questions, will be checked. If assumptions are violated, data transformation will be considered. The independence of observations will be checked using graphical methods. Normality checks will be performed using histograms of standardized residuals, normal probability plots (Q-Q Plots), and Kolmogorov-Smirnov test. Also, linearity between each pair of the variables will be assessed using scatter plots. In addition, homoscedasticity will be investigated using bivariate scatter plots. Further, multicollinearity will be examined using variance inflation factors, tolerance, and a correlation matrix among independent variables. Special attention will be placed on correlation coefficient matrix with all the independent variables indicates correlations of .75 or higher. Multicollinearity is likely to occur when there are many independent variables in a multiple regression analysis. To reduce number of the independent variables, if multicollinearity is discovered, dropping one of the two variables that are highly correlated or combining highly correlated variables to be one single subscale score will be considered.

## **6.7 DATA ANALYSIS PROCEDURES**

Bivariate correlations will be estimated between each pair of independent variables and dependent variables. Pearson's product moment coefficient will be computed for interval or ratio level of measurement data with normal distribution. Spearman's rank-order correlation coefficient will be chosen for the data with ordinal level of measurement or non-normal data with interval or ratio level of measurement.

**Aim 1:** Examine the relationship of *sum score of intervention fidelity* and the symptom representations (symptom severity, symptom consequences, and symptom-related distress), after controlling for baseline symptom representations and socio-demographic characteristics.

Hierarchical multiple linear regression analysis will be performed. The variables to be controlled (socio-demographic characteristics and baseline symptom representation score) will be entered into the model in the first block and the predictor of interest (*sum score of intervention fidelity*) will be entered in the second block. Key statistics, including F test statistics and the estimated unstandardized and standardized regression coefficients with their standard errors, will be generated. The percentage of variance in the dependent variable that can be accounted for by all the predictors together ( $R^2$ ), adjusted  $R^2$ , and MSE will also be produced. The change in  $R^2$  will be examined to evaluate how much predictive power was added to the covariate only model by the addition of *sum score of intervention fidelity* in second variable block. Model assessment performing residual analyses and examinations of possible influential observations and the extent of influence on fitted/predicted values, parameter estimates, and precision/variance estimates will also be produced.

**Aim 2:** Examine the relationship between *independent variables of interest* (thirteen *intervention fidelity score* of each thirteen subscale of the WRITE Symptoms fidelity instrument) and the symptom representations (symptom severity, symptom consequences, and symptom-related distress), after controlling for baseline symptom representations and socio-demographic characteristics.

Similar analytic approach as presented for Aim 1 will be performed. The variables to be controlled will be entered into the model in the first block and *all intervention fidelity scores* of each thirteen subscale of the WRITE Symptoms fidelity instrument, the predictor of interest, will be entered in the second block.

## **6.8 SAMPLE SIZE JUSTIFICATION**

The sample size of this present study is fixed (N=160). A sample size of 160 achieves 80% power to detect an R-Squared of 0.05 attributed to 1 independent variable(s) using an F-Test with a significance level (alpha) of 0.05. The variables tested are adjusted for additional 4 independent variables.



## **APPENDIX A**

### **WRITE SYMPTOMS FIDELITY INSTRUMENT**

## FIDELITY ASSESSMENT

Focus on interactions around a single symptom on the message board (randomly selected) for the first 29 items. Then respond to the last 26 items based on the full set of postings available at the time of review.

<b>Single symptom evaluation</b>					
<i><b>Representational Assessment</b></i>		<b>0</b> (Not at all)	<b>1</b> (Some)	<b>2</b> (Completely)	<b>Comments/notes</b>
1.	Did the nurse assess the participant's perception of the identity of her symptom?				
2.	Did the nurse assess the participant's perception of the cause of her symptom?				
3.	Did the nurse assess the participant's perception of the timeline of her symptom?				
4.	Did the nurse assess the participant's perception of the consequences of her symptom?				
5.	Did the nurse assess the participant's perception of the ways to cure/control her symptom?				
6.	Did the nurse assess the participant's emotions related to her symptom?				
<i><b>Exploring Concerns, Misconceptions, Gaps in Knowledge</b></i>		<b>0</b> (Not at all)	<b>1</b> (Some)	<b>2</b> (Completely)	<b>Comments/notes</b>
7.	Did the nurse discuss at least one concern, misconception, confusion and/or gap (either individual or common) relevant to the participant's previous posts?				
8.	Did the nurse miss opportunities to explore concerns, misconceptions, confusions and/or gaps presented by the participant? (Reversed score)				
<i><b>Creating conditions for conceptual change</b></i>		<b>0</b> (Not at all)	<b>1</b> (Some)	<b>2</b> (Completely)	<b>Comments/notes</b>
9.	Symptoms as "controllable". Did nurse				

	convey message that the participant could have control over her symptom?  (we have information that we hope will help them get better control of symptoms)				
10.	Did the nurse discuss how concerns/misconceptions/gaps in knowledge (either individual or common) can interfere with effective symptom management?				
11.	Did the nurse discuss alternative ways of thinking about concerns, misconceptions, confusions and/or gaps that might help the participant feels more comfortable talking with her HCT?				
12.	Did the nurse encourage the use of new symptom management strategies in order to reduce the impact that symptoms have on the participant's life?				
<b><i>Provides new information</i></b>		<b>0</b> (Not at all)	<b>1</b> (Some)	<b>2</b> (Completely)	<b>Comments/notes</b>
13.	Did the nurse refer the participant to the symptom care guide (SCG)?				
14.	Did the nurse give an overview of the symptom care guide by highlighting examples of the types of information/strategies that the participant might find useful?				
15.	Did the nurse discuss information from the SCG in more detail on the message board?				
16.	Did the nurse discuss the importance of talking with local HCT about symptoms and symptom management strategies?				
<b><i>Setting Goals &amp; Strategies</i></b>		<b>0</b> (Not at all)	<b>1</b> (Some)	<b>2</b> (Completely)	<b>Comments/notes</b>
17.	Did the nurse work with the participant to set a SMART goal (e.g. specific, measurable, attainable, realistic, timely) for her symptom?				
18.	Did the nurse ask the participant to				

	identify at least one specific strategy to help her reach her goal?				
19.	Did the nurse seek input from the participant regarding selection strategies?  (strike balance between providing specific information on possible strategies without prescribing)				
20.	Did the nurse provide guidance in breaking down broad strategies into a specific symptom management plan made up of small, action-oriented steps?  (This could include a specific plan for how to start a new self-care strategy or specific plan for communicating with HCT about medical/pharmacologic interventions.)				
21.	Did the nurse validate that final goals and strategies are acceptable to the participant?				
<b>Summary</b>		<b>0</b> (Not at all)	<b>1</b> (Some)	<b>2</b> (Completely)	<b>Comments/notes</b>
22.	When the nurse submits the symptom care plan, did the nurse provide a summary of the ways that engaging in this systematic process (the Representational Approach) and trying new strategies can help participant get better control over symptoms?				
23.	Did the nurse orient the participant to the process of implementing and evaluating new strategies?  (Try strategies over 2 week period; evaluate how new strategies are working; track any concerns or barriers to using new strategies; plan to review on message board in 2 weeks).				

<i>Symptom follow up/Goal Strategy Review</i>		<b>0</b> (Not at all)	<b>1</b> (Some)	<b>2</b> (Completely)	Comments/notes
24.	Did the nurse assess whether the participant attempted to implement selected strategies?				
25.	Did the nurse assess barriers or concerns about use of selected strategies?				
26.	Did the nurse assess the effectiveness of the selected strategies?				
<i>Goal &amp; Strategy Revision</i>		<b>0</b> (Not at all)	<b>1</b> (Some)	<b>2</b> (Completely)	Comments/notes
27.	Did the nurse ask the participant whether she would like to modify her goals and strategies?				
28.	<p>a. If the participant was successful with previous strategies and does not want to make any changes, did the nurse affirm successes before skipping to #29?</p> <p>b. If participant was successful with previous strategies, but wants to add additional strategies, did the nurse work with participant to identify potential new strategies?</p> <p>c. If previous strategies were tried, but were not effective, did the nurse work with the participant to identify potential new strategies?</p> <p>d. If previous strategies were not tried or not used consistently, did the nurse assist participant to identify ways to overcome any reported barriers to implementing strategies?</p>				
29.	Did the nurse emphasize the need for adjustments to plan over time to achieve good symptom management?				

Overall evaluation of full intervention					
<i>Teaching the Representational Approach Process</i>		0 (Not at all)	1 (Some)	2 (Completely)	Comments/notes
30.	Did the nurse inform the participant regarding how the intervention will help her get better control of her symptom?  (how the intervention works)				
31.	Did the nurse discuss a tentative agenda with the participant at the beginning of the session?				
32.	Did the nurse teach the participant the process of the representational approach during the 2 <sup>nd</sup> and/or 3 <sup>rd</sup> symptom?				
33.	Did the nurse encourage the continued use of the representational approach in the future?				
<i>Consistent flexible application of protocol</i>		0 (Not at all)	1 (Some)	2 (Completely)	Comments/notes
34.	Did the nurse demonstrate individualization in the protocol based on participant's responses?				
35.	Was the nurse flexible in addressing participant's questions/ problems as they arose?				
36.	Did the nurse break down complex information or experiences into manageable pieces?				
37.	Did the nurse use probes appropriately?  (probe when more information needed, not probe when detail provided spontaneously)				

<b><i>Therapeutic alliance</i></b>		<b>0</b> (Not at all)	<b>1</b> (Some)	<b>2</b> (Completely)	<b>Comments/notes</b>
38.	Did the nurse use language regarding cooperation and working together?				
39.	Did the nurse <i>avoid</i> emotional/difficult topics introduced by the participant? (Reverse Score)				
40.	Did the nurse present alternative views or opinions in a non-judgmental manner?				
41.	In general, did the nurse ask questions which were open-ended?				
42.	Did the nurse invite the participant to ask questions?				
43.	Did the nurse periodically check that her understanding/interpretation of the participant's experience was accurate?				
44.	Did the nurse end each phase by summarizing the main points covered?				
<b><i>Fidelity to scope of intervention (symptom management &amp; nursing practice)</i></b>		<b>0</b> (Not at all)	<b>1</b> (Some)	<b>2</b> (Completely)	<b>Comments/notes</b>
45.	Did the nurse <i>avoid</i> giving advice on cancer or cancer treatment?				
46.	Did the nurse <i>avoid</i> giving <u>prescriptive</u> advice on medical/pharmacologic interventions?				
47.	Did the nurse <i>avoid</i> recommending strategies not included in algorithms/SCGs?				
48.	Did the nurse ask appropriate safety questions based on symptom algorithm?				
49.	Did the nurse tell the participant to contact HCT if any new symptoms arise or if symptom worsens?				

<i>Asynchronous web-based skills</i>		<b>0</b> (Not at all)	<b>1</b> (Some)	<b>2</b> (Completely)	Comments/notes
50.	Did the nurse respond to participant's posts within 24 hours 5 days/week?				
51.	Did the nurse use strategies to make text more reader-friendly?  (e.g. use of white space, numbering/bullets, organization of messages by symptom, use of descriptive subject lines)				
52.	Did the nurse offer to break up information into smaller posts?				
53.	In general, were the numbers of questions asked by the nurse in each post appropriate to the number of issues raised in the participant's post?				
54.	Did the nurse match tone, reading level, use of humor to that of the participant?				



## **APPENDIX B**

### **GENERAL INSTRUCTION FOR RATING AND CODING RULES FOR EACH ITEM**

### **General instruction for rating**

Please review the following instructions before rating.

1. Before rating the intervention session, read through the intervention thoroughly at least once, from the beginning to the end of the intervention session.
2. If you (as the rater) are not immediately able to determine how extensively the interventionist performed the target behaviors on each particular item, do not score that item until you have found the information you need or are confident that the behavior was not performed. This may require re-reading the intervention in its entirety, or portions of it. The information being sought will not necessarily appear in the same place nor in the same style as the intervention samples you read previously.
3. If you (as the rater) are not sure whether a particular behavior was performed at the maximum level possible, but it was performed to a noticeable level, then that item should be scored as a 1. This is done to prevent over-rating an interventionist's performance and, equally as important, to avoid under-rating their performance

## **Coding rules for each item**

### **Behaviors unique and essential to the WRITE Symptoms intervention (9 subscales)**

#### **Subscale 1: representational assessment**

Goal: To evaluate the extent to which the interventionist encouraged the participant to describe representations of her symptom along the six dimensions of representations: identity, cause, timeline, consequences, cure or control, and emotion. The goal is to get a clear picture of the participant's understanding of the symptom and identify any concerns, misconceptions, or gaps. This subscale captures the extent to which the nurse encourages participant to describe representations of health problem (e.g., symptoms or illness) along the six dimensions of Representational Approach: identity, cause, timeline, consequences, cure or control, and emotions.

The nurse is expected to use broad questions, initially, as follows.

“I would like you to tell me about your '**symptom**'. Don't worry about writing too much – tell me in as much detail as possible. Often it is helpful if you describe a typical day or tell me how the '**symptom**' is affecting your life. Just tell the story of your experience.”

Then, the nurse needs to assess symptom representations in detail by using specific questions (as detailed in each item) to elicit more detailed information on dimensions that were not spontaneously offered.

**Item 1: Did the nurse assess the participant's perception of the identity of her symptom?**

Definition of identity: What the symptom feels like to the participant including severity and other descriptors.

2 = The nurse completely assessed the participant's perception of the identity of her symptom.

1 = The nurse partially assessed the participant's perception of the identity of her symptom.

0= The nurse did not assess the participant's perception of the identity of her symptom.

**Exemplars:**

Score 2:

- Nurse: What does your fatigue feel like and how severe is it?

Score 0:

- The nurse did not ask about the participant's perception of the identity of her symptom.

**Item 2: Did the nurse assess the participant's perception of the cause of her symptom?**

Definition of cause: What the participant believes is causing the symptom.

2 = The nurse completely assessed the participant's perceptions about the likely cause or causes of her symptom.

1 = The nurse partially assessed the participant's perceptions about the likely cause or causes of her symptom (e.g. did not probe appropriately based on participants initial response).

0 = The nurse did not assess the participant's perceptions about the likely cause or causes of her symptom at all.

**Exemplars:**

Score 2:

- Nurse: “There are so many things that can cause itchy skin. One of the first things to do is to try to figure out the cause. What do you think is causing your itchy skin?  
What medications are you taking? Anything new? Also, have you started using any new soaps or detergents? Any new skin products?”

Score 0:

- The nurse did not assess the participant's perception of the cause of her symptom.

**Item 3: Did the nurse assess the participant's perception of the timeline of her symptom?**

Definition of timeline: The participant's belief about the temporal nature of the symptom and how long she expects it to last

2 = The nurse completely assessed the participant's perception of the timeline of her symptom.

1 = The nurse partially assessed the participant's perception of the timeline of her symptom.

0 = The nurse did not assess the participant's perception of the timeline of her symptom.

**Exemplars:**

Score 2:

- Nurse: "What has been the timeframe of your symptom? For example: how long have you had it, what has been the pattern?" Another way of asking might be "When did you first notice the symptom and does it follow any sort of pattern?"

Score 0:

- The nurse did not assess the participant's perception of the timeline of her symptom.

**Item 4: Did the nurse assess the participant's perception of the consequences of her symptom?**

Definition of consequences: The participant's belief about short- and long-term consequences of the symptom.

2 = The nurse completely assessed the participant's perceptions of consequences of her symptoms on her life. .

1 = The nurse partially assessed the participant's perceptions about how the symptom has consequences on her physical and social functioning.

0 = The nurse did not assess the participant's perceptions about how the symptom has consequences on her physical and social functioning.

**Exemplars:**

Score 2:

Nurse: "Fatigue can affect so many aspects of a woman's life. It sounds like grocery shopping is a big hurdle for you. Are there other ways that fatigue affects your life?" Or could further probe with: "Are there other things your fatigue has prevented you from doing that you enjoy or need to do?"

Score 0:

- The nurse did not assess the participant's perception of the consequences of her symptom.

**Item 5: Did the nurse assess the participant's perception of the ways to cure/control her symptom?**

Definition of cure/control: The participant's perception about how much control she believes she has over the symptom and things the participant has done to try to control the symptom, how well those have worked and any concerns regarding their use.

2 = The nurse completely assessed the participant's perceptions about how she currently tries to manage the symptoms, and how much control she feels she has over the symptom.

1 = The nurse partially assessed the participant's perceptions about how she currently tries to manage the symptoms, and how much control she feels she has over the symptom.

0 = The nurse did not assess the participant's perceptions about how she currently tries to manage the symptoms, and how much control she feels she has over the symptom.

**Exemplars:**

Score 2:

- Nurse: "What kinds of things have you tried to manage this symptom? How does it work? "What have you tried in the past? What helped? What didn't help? What problems or concerns have you had in trying to manage it?"

Score 0:

- The nurse did not assess the participant's perception of the ways to cure/control her symptom.



**Item 6: Did the nurse assess the participant's emotions related to her symptom?**

2 = The nurse completely assessed the participant's emotions related to her symptom.

1 = The nurse partially assessed the participant's emotions related to her symptom.

0 = The nurse did not assess the participant's emotions related to her symptom.

**Exemplars:**

Score 2:

- Nurse: You said you feel bad because of your fatigue. Can you tell me more about how the fatigue affects you emotionally? I would like to understand more about what you mean by feeling bad.

Score 0:

- The nurse did not assess the participant's emotions related to her symptom.

### **Subscale 2: exploring concerns, misconceptions, gaps in knowledge**

**Goal:** To evaluate the extent to which the interventionist encouraged the participant to think and talk about what experiences led to the development of any identified concerns, misconceptions, or gaps. The goal of this subscale is to understand how any identified concerns, misconceptions, or gaps developed. This subscale captures the extent to which the nurse encouraged the participant to think and talk about what experiences led to the development of any misconceptions or confusions.

**Notes:** The nurse is expected to explore participant's beliefs and experiences related to a concern, misconception, confusion and/or a gap related to symptoms or symptom management. These beliefs could be written spontaneously by the participant in previous posts (individual) or could be common concerns that the patient agreed with on the baseline Symptom Management Barriers questionnaire. If the participant does not indicate any misconceptions, confusion or concerns about her symptom management approach, the nurse is expected to offer a general comment about one or more of the concerns the participant agreed with from the Symptom Management Barriers Questionnaire (SMBQ) and focus discussion on the SMBQ item(s) most relevant to the symptom being addressed on the message board.

**Item 7: Did the nurse discuss at least one concern, misconception, confusion and/or gap (either individual or common) relevant to the participant's previous posts?**

2 = The nurse addressed at least one concern/gap/confusion related to either a spontaneously offered concern brought up in (a) previous post(s) by the participant or one of the standard concerns from baseline questionnaires (the participant's responses to the Symptom Management Barriers Questionnaire (SMBQ)).

1 = The nurse partially addressed at least one concern/gap/confusion related to either a spontaneously offered concern brought up in (a) previous post(s) by the participant or one of the standard concerns from baseline questionnaires.

0 = The nurse did not address a concern/gap/confusion related to either a spontaneously offered concern brought up in (a) previous post(s) by the participant or one of the standard concerns from baseline questionnaires at all.

**Exemplars:**

Score 2:

- Nurse: "I am wondering about the pain you have during the night. Have you had any problems taking pain medicine for arthritis? To me, you seem hesitant to use the pain medicine. Do you have any concerns about taking the medication?"

Score 0:

- The nurse never addressed a concern/gap/confusion related to either a spontaneously offered concern brought up in (a) previous post(s) by the participant or one of the standard concerns from baseline questionnaires.

**Item 8: Did the nurse miss opportunities to explore concerns, misconceptions, confusions and/or gaps presented by the participant? (Reverse score)**

2 = The nurse completely missed/ignored (did not explore) a significant concern/ misconception/ confusion/ gap that the participant brought up in (a) previous post(s).

1 = The nurse partially acknowledged the significant concern/misconception/confusion/gap presented by the participant.

OR

1 = The nurse did respond to some concern/misconception/confusion/gap presented by the participant; but, there was at least one significant concern/misconception/confusion/gap that was not explored.

0 = The nurse did not acknowledge and explored significant concerns/misconceptions/confusions/gaps presented by the participant.

**Note:** This item is different from item number 7 because it adds an important piece not included in item number 7. Item number 7 requires that nurses address at least one concern/gap/confusion, but it doesn't matter whether it is a spontaneously offered concern or one of the standard concerns from baseline questionnaires. Item 8 captures whether the nurse missed an important concern/gap/confusion that was spontaneously offered by the patient.

**Exemplars:**

Score 2:

- The nurse did not explore a significant concern/ misconception/ confusion/ gap when it was brought up by the participant in (a) previous post(s).

Score 0:

- Nurse: “In your previous post, you mentioned you have tried to go without Miralax. I am wondering why you have tried to avoid using the Miralax? Constipation can lead to other problems, beyond the discomfort itself, and as you've found out .....it's good to stay on top of that. Could you please tell me more if you have had any concerns or problems about using the Miralax?”

### **Subscale 3: creating conditions for conceptual change**

Goal: To evaluate the extent to which the interventionist helped the participant to recognize the limitations of her current representations -- i.e., ways in which gaps or confusions may be contributing to inadequate symptom management. This subscale captures the extent to which the nurse helps the patient recognize the limitations of current conceptions; i.e., ways in which gaps or confusions may be having negative effects.

**Item 9: Symptoms as “controllable” Did the nurse convey the message that the participant could have control over her symptom?**

2 = The nurse used a statement regarding there are some strategies that could help the participant get better control over her symptoms.

1 = The nurse used a statement regarding there are some strategies that could help the participant get better control over her symptoms; but not convincingly enough

0 = The nurse did not made a statement regarding there are some strategies that could help the participant get better control over her symptoms at all.

**Exemplars:**

Score 2:

- Nurse: “I may have some strategies you are not familiar with that may be able to help you be more successful. I would like to give you some suggestions that may not cure your memory problems, but will help you find ways to manage and get more control so that your memory problems will possibly have less of an effect on your daily life.”

Score 0:

- There was no made statement regarding there would be some strategies that could help the participant get better control over her symptoms.



**Item 10: Did the nurse discuss how concerns/misconceptions/gaps in knowledge (either individual or common) can interfere with effective symptom management?**

2 = The nurse comprehensively discussed with the participant ways in which concerns/misconceptions/gaps in knowledge interfere with effective symptom management strategies or outcomes. The nurse addressed the potential relationship between the concerns/misconceptions/gaps in knowledge and difficulties in achieving optimal symptom management.

1 = The nurse partially discussed with the participant ways in which concerns/misconceptions/gaps in knowledge interfere with effective symptom management strategies or outcomes.

0 = The nurse did not discuss with the participant ways in which concerns/misconceptions/gaps in knowledge interfere with effective symptom management strategies or outcomes at all.

**Exemplars:**

Score 2:

- Nurse: “I am wondering about the pain you have during the night. Many women don't like to take a lot of medicines for a variety of reasons. Have you had any problems taking pain medicine for arthritis? It seems that the pain you are experiencing later in the night prevents you from getting the sleep you need to feel rested and comfortable, which affects how much energy you have to do the things you want, like grocery shopping and the important work for your church.”

Score 0:

- There was no statement regarding how concerns/misconceptions/gaps in knowledge can interfere with effective symptom management.

**Notes:** The key for the rater is to check if the nurse made a link between concerns/misconceptions/gaps in knowledge and the ineffective symptom management the participant is experiencing, and to determine if the nurse discussed the impact of these beliefs/barriers on participant's ability to manage symptoms well.

**Item 11: Did the nurse discuss alternative ways of thinking about concerns, misconceptions, confusions and/or gaps that might help the participant feel more comfortable talking with her HCT?**

2 = The nurse made a comprehensive statement which may help participant *feel more comfortable* talking with their HCT.

1 = The nurse made a statement which might help participant *feel more comfortable* talking with their HCT; but, not comprehensively.

0 = The nurse did not make a statement which might help participant *feel more comfortable* talking with her HCT.

**Exemplars:**

Score 2:

- Nurse: “Many women talk about feeling like they are whining or complaining when they tell someone about the symptoms they are experiencing. However, your doctor and nurses can’t know how you are doing unless you tell them about it. Be sure to keep them in the loop. They want you to be as comfortable as you can be and the information helps them stay informed about your condition.”

Score 0:

- There was no statement regarding discussing alternative ways of thinking about concerns, misconceptions, confusions and/or gaps that might help the participant feels more comfortable talking with her HCT.

**Item 12: Did the nurse encourage the use of new symptom management strategies in order to reduce the impact that symptoms have on the participant's life?**

2 = The nurse conferred with the participant regarding how new ways of approaching symptom management could solve some of the current problems by making statements concerning (1) there are other things that can be done to help participant get better control over symptoms, and (2) the importance of trying new strategies in order to solve current problems/reduce consequences.

1 = The nurse conferred with the participant regarding how new ways of approaching symptom management could solve some of the current problems, but not comprehensively address two of these topics (1) there are other things that can be done to help participant get better control over symptoms, and (2) the importance of trying new strategies in order to solve current problems/reduce consequences.

0 = The nurse did not confer with the participant regarding how new ways of approaching symptom management could solve some of the current problems.

**Exemplars:**

Score 2:

- Nurse: "As you read through this guide you will see some strategies you have already talked about. But, you will also see some new strategies you haven't tried yet or maybe a new way to think about a strategy you already use. It may be difficult to eliminate fatigue, but by making small changes, which is important for symptom management, it is possible to reduce fatigue."

Score 0:

- There was no statement made about encouraging the use of new symptom management strategies.

#### **Subscale 4: providing new information**

Goal: To evaluate the extent to which the interventionist provided new information to fill in gaps in knowledge, clarify confusions, and replace current misconceptions. This subscale captures the extent to which the nurse presents credible information to fill in gaps in knowledge, clarify confusions, discuss benefits associated with acting on new information, and replace current misconceptions with credible and beneficial information. The nurse is expected to use the best empirical evidence and clinical practice guidelines from algorithms/symptom care guides to help the participant feel more comfortable/confident discussing symptoms and potential solutions with her HCT.

**Item 13: Did the nurse refer the participant to the symptom care guide?**

2 = The nurse instructed the participant to read the symptom care guide and highlighted the credibility of the symptoms care guide by making a statement regarding the information in the guide is updated through a literature review to ensure that it reflects best current evidence.

1 = The nurse only informed the participant to read the symptom care guide; but the nurse did not mention credibility of the self-care guide.

0 = The nurse did not instruct the participant to read the symptom care guide.

**Exemplars:**

Score 2:

- Nurse: “What I would like to do now is share some information with you about abdominal bloating. There are several strategies that may help you that can be found in our Abdominal Bloating Symptom Care Guide (SCG). The information in these guides comes from current research and best clinical practice. You can find them under the "Symptom Care Guide" tab along the top of the homepage. You'll see the three symptoms you want to work on and also a link for other guides...”

Score 1:

- Nurse: “What I would like you to read is the Abdominal Bloating Symptom Care Guide (SCG). You can find it under the "Symptom Care Guide" tab along the top of the homepage.”

Score 0:

- There was no statement about referring the participant to the self-care guide.

**Item 14: Did the nurse give an overview of the symptom care guide by highlighting examples of the types of information/strategies that the participant might find useful?**

2 = The nurse comprehensively gave at least one example of the types of information/strategies that the participant might find useful by underlining the types of information/strategies that fit well with the participant's interest/situation.

1 = The nurse partially gave at least one example of the types of information/strategies that are relevant to the current working symptom.

0 = The nurse did not give examples of the types of information/strategies that are relevant to the current working symptom.

**Exemplars:**

Score 2:

- Nurse: "There are many things that contribute to cancer-related fatigue. It is the most common side-effect of cancer and its treatment...and it is the most common symptom women talk about. The physical aspects of your illness have a big impact on the levels of your fatigue. Research has shown that individuals engaging in regular exercise report lessened feelings of fatigue and increased energy levels."

Score 0:

- There was no statement regarding an overview of the symptom care guide by highlighting examples of the types of information/strategies that the participant might find useful.



**Item 15: Did the nurse discuss information from the SCG in more detail on the message board?**

2 = When the potential strategies, which the participant might want to try, were identified, the nurse discussed with the participant in more detail how to implement the strategies.

1 = When the potential strategies, which the participant might want to try, were identified, the nurse discussed with the participant how to implement the strategies; but not in detail.

0 = When the potential strategies, which the participant might want to try, were identified, the nurse did not discuss with the participant how to implement the strategies.

**Exemplars:**

Score 2:

- Nurse: “For the restorative technique, I’d like to suggest that you do it 3-4 times a week or more if you like. Schedule 20-30 minutes to engage in an activity like watching wildlife or spending time in a natural setting, or reading something light and relaxing that doesn't require you to think and process. It’s a simple idea, but needs to be done on a regular schedule. Think of it as a treatment and you get the "dose” by doing a peaceful, relaxing activity for a scheduled period of time on a regular basis.”

Score 1:

- Nurse: “The "**4 P's**" (Plan, Prioritize, Pacing and Positioning) that are discussed in the fatigue symptom care guide are a helpful way of thinking about **conserving** your energy. Maybe you should set your plan to follow the 4 P’s to help you feel better.”

Score 0:

- There was no discussion about information from the SCG in more detail.

**Item 16: Did the nurse discuss the importance of talking with local HCT about symptoms and symptom management strategies?**

2 = The nurse comprehensively encouraged the participant to discuss with local HCT and emphasized the importance of talking with local HCT about symptoms and symptom management strategies.

1 = The nurse partially encouraged the participant to discuss with local HCT about symptoms and symptom management strategies.

0 = The nurse did not tell the participant to discuss with local HCT about her symptoms and symptom management strategies.

**Exemplars:**

Score 2:

- Nurse: “I would like to suggest you discuss your constipation with your HCT during your next visit. It is important to continually let your health care team know how you are managing with symptoms and side effects. For symptoms like constipation, they cannot know how you are doing unless you tell them. Communicating more fully with your HCT may result in improved management of the constipation.”

Score 1:

- Nurse: “I would like to suggest you discuss your constipation with your HCT during your next visit.”

Score 0:

- There was no statement made to encourage the participant to discuss with local HCT.

### **Subscale 5: setting goals and strategies**

Goal: To evaluate the extent to which the interventionist worked with participant to develop goals related to improving the symptom and specific strategies for reaching those goals. This subscale captures the extent to which the nurse worked with the participant to develop goals related to improving the health problem and specific strategies for reaching those goals. The nurse is expected to help the participant to put together a specific plan for talking with her HCT regarding strategy selection from SCGs and accept and use different strategies for managing symptoms.

**Item 17: Did the nurse work with the participant to set a SMART goal (e.g. specific, measurable, attainable, realistic, and timely) for her symptom?**

2 = The nurse provided the participant comprehensive guidance for making a goal related to improving her symptom “SMART” (specific, measurable, attainable, realistic, and timely).

1 = The nurse provided the participant guidance for making a goal related to improving her symptom, but the guidance might not be comprehensive; and the goal did not demonstrate the SMART characteristics: specific, measurable, attainable, realistic, and timely.

0 = The nurse did not provide the participant guidance for making a goal related to improving her symptom “SMART”.

**Exemplars:**

Score 2:

- Nurse: “The **goal** should be a statement about what you hope to accomplish or want to happen related to your hot flashes. We like to use SMART guidelines for writing goals. I'd like you to write a goal for addressing fatigue with the following guidelines in mind. I will help you work through this step of the process. To be "SMART" write a goal that is:

S - Specific. Enough detail that the goal gives you real direction.

M - Measurable. How will you know if you met your goal? For example, if your fatigue decreases?

A - Attainable; something you can accomplish.

R - Realistic; is it something that fits in your life and how you do things?

T - Timely; put a target date in your goal. Something to work for in a period of time.

We often start with 2 weeks for the first goal because we'll check back on progress in that period of time, but you can put anything you want. The goal should reflect enough detail that when you look at it later you can tell if you have made progress or not.”

Score 0:

- There was no statement regarding providing the participant guidance for making a goal related to improving her symptom “SMART”.

**Item 18: Did the nurse ask the participant to identify at least one specific strategy to help her reach her goal?**

2 = The nurse asked the participant to select one or more new strategies to try.

1 = The nurse partially asked the participant to select one or more new strategies to try.

0 = The nurse did not ask the participant to select one or more new strategies to try.

**Exemplars:**

Score 2:

- Nurse: “We also have some information about fatigue in the **Symptom Care Guide** for Fatigue. Please give some thought to which strategies would best fit in your life and what type of goal you might have for your fatigue. What strategies would you like to try?”

Score 0:

- There was no statement regarding asking the participant to identify at least one specific strategy to help her reach her goal.



**Item 19: Did the nurse seek input from the participant regarding selection strategies?**

(Strike a balance between providing specific information on possible strategies without prescribing)

2 = The nurse helped the participant to put together a specific plan for managing symptoms by striking a balance between providing specific information on possible approaches to treatment without prescribing and suggesting as a “knowledgeable expert/coach” not a personal clinician.

1 = The nurse helped the participant to put together specific plan for managing symptoms. But, there were *some* strategies that were the result of the nurse-provided specific information on possible approaches with prescribing and suggesting as a personal clinician.

0 = The nurse did not seek input from the participant to help her put together a specific plan for managing symptoms, rather she persisted in talking about and providing the participant her own concept of strategies.

**Exemplars:**

Score 2:

- Nurse: “You outlined several excellent strategies for helping with your sleep and it sounds like you would like to continue (or restart) these. Here is what I put together. It contains a few suggestions with all of the strategies you have talked about over the last few days.”
  - Set up a schedule for getting up at a regular time and going to bed at a regular time (When will you make this schedule?)
  - Limit naps during the day (to how many?) to prevent "short nights".

- Limit fluids right before bedtime. (At what time of day would you think about cutting back? This is something you may want to run by your health care team (HCT) to be sure it's OK, especially as it relates to chemo and diabetes.)
- Wii-Fit: 10 minutes/day 3x a week. This is great. When do you think you'd like to start doing this?

“See if you think I have this right. Let me know what additions or changes you want to make. Are there details you can add to make the strategies more specific?”

Score 0:

- Nurse: “Here is what I put together for helping with your sleep.”
  - Set up a schedule for getting up and going to bed at a regular time. The sooner you chose times and start the better you may feel.
  - Limit naps during the day to prevent "short nights".
  - Start exercising 10 minutes/day 3x a week.

**Notes:** The nurse does not persist in talking about her own concept of strategies. Strategies are generated from the participant’s ideas/circumstances. The participant is the expert about her situation. The nurse seeks collaboration and gives the participant the opportunity to explore and solve problems for herself. In general, the nurse should work on strategy selection by asking a question of the participant, leading the participant into the process of problem-solving, and relies on the participant’s personal resources and interests to find solutions to her issues.

**Item 20: Did the nurse provide guidance in breaking down broad strategies into a specific symptom management plan made up of small, action-oriented steps?**

(This could include a specific plan for how to start a new self-care strategy or specific plan for communicating with HCT about medical/pharmacologic interventions.)

2 = The nurse helped the participant put together a specific plan for managing symptoms by providing guidance in breaking down broad strategies listed in the self-care guide into discrete actions (e.g. what, when, where, how, how many, how long, and how often) that need to be taken to implement the strategy.

1 = The nurse helped the participant put together a specific plan for managing symptoms by providing guidance in breaking down broad strategies listed in the self-care guide into *some* discrete actions; but not comprehensively.

0 = The nurse did not help the participant break down broad strategies listed in the self-care guide into discrete actions.

**Exemplars:**

Score 2:

- Nurse: “Here is a draft of what I have put together of strategies you may want to try for managing your symptom. In order to help you implement your selected strategies more easily, I would like you to answer more questions (in **bold**). Please answer the questions so you can make your plan more specific:
  - Eat lots of veggies and fruit (**How much? How often?**)

- Exercise with cardio and core strength routine (**How long are sessions? How often? When will you start?**)
- Look at schedule and see where you could fit in Yoga. (**Could you start with few minutes of stretching? How many days/week? When will you start?**)

Score 0:

- Here is what I put together of all the strategies you want to try:
  - Discuss your symptom with your doctor
  - Drink more fluids
  - Avoid using products with alcohol on skin
  - Try to keep cooler

**Item 21: Did the nurse validate that final goals and strategies are acceptable to the participant?**

2 = The nurse checked with the participant if both final goals and strategies are acceptable to participant before submitting Symptom Care Plan.

1 = The nurse checked with the participant if only final goals or only strategies are acceptable to participant before submitting Symptom Care Plan.

0 = The nurse did not validate if final goals and strategies are acceptable to patient before submitting Symptom Care Plan.

**Exemplars:**

Score 2:

- Nurse: “I placed these goals and strategies in your Fatigue Care Plan (Draft). You will find this under the **My Symptom Care Plan** tab that is along the top of your study homepage.  
Click on that tab and you will see the symptoms we are working on.  
Click on Fatigue. Read through the plan and let me know if this looks accurate to you. Do we need to make any changes?”

Score 1:

- Nurse: “Let me know if the goals in your Symptom Care Plan (Draft) look right to you.”

Score 0:

- There was no statement about validating if final goals and strategies are acceptable to the participant.

**Notes:** The decision for final goals and strategies is up to the participant.

### **Subscale 6: summary**

Goal: To evaluate the extent to which the interventionist discussed benefits associated with acting on new information.

**Item 22: When the nurse submits the symptom care plan, did the nurse provide a summary of the ways that engaging in this systematic process (the Representational Approach) and trying new strategies can help the participant get better control over symptoms?**

2 = When the nurse submitted the symptom care plan, she summarized that engaging in the Representational Approach and trying new strategies can help the participant get better control over symptoms by making statements regarding these processes: (1) thinking about how her symptoms are affecting her life, (2) planning her goals for better symptom management, and (3) selecting the strategies that she would like to try based on information available in the Symptom Care Guide for her bothersome symptoms.

1 = When the nurse submitted the symptom care plan, she summarized that engaging in the Representational Approach and trying new strategies can help the participant get better control over symptoms. But, only some of these topics were addressed: (1) think about how her symptoms are affecting her life, (2) plan her goals for better symptom management, and (3) select the strategies that she would like to try based on information available in the Symptom Care Guide for her bothersome symptoms.

0 = When the nurse submitted the symptom care plan, she did not summarize how engaging in the Representational Approach and trying new strategies can help the participant get better control over symptoms.

**Exemplars:**

Score 2:

- Nurse: “I would like to take a moment to reflect a bit on where we have come in the past couple weeks. We discussed your difficulties with abdominal bloating and how it affects



your ability to eat, drink and move about. We also discussed your concerns about talking with your health care team and ideas about medications, and how concerns can sometimes interfere with the best care for your symptoms. You took time to think and "stew" about this and that's an important part of this process. More importantly, this program has taken you through a systematic process of setting goals for improving your symptoms and selecting strategies to try to reach those goals so you can have a better quality of life.”

Score 1:

- Nurse: “I want to take a moment to reflect on how we are working through this process together. You're doing a great job of describing what's going on and how your symptom affects your life. I can see you are thinking about things and working to come up with realistic plans.

Score 0:

- There was no statement about a summary of the ways that engaging in this systematic process (the Representational Approach) and trying new strategies can help the participant get better control over symptoms.

**Notes:** This item is about only “When the nurse submits the symptom care plan”; so, a rater should score based on information provided in this specific post.

**Item 23: Did the nurse orient the participant to the process of implementing and evaluating new strategies?**

(Try strategies over two-week period; evaluate how new strategies are working; track any concerns or barriers to using new strategies; plan to review on message board in 2 weeks).

2 = The nurse asked the participant to implement and evaluate new strategies by addressing all of these four topics:

- Trying strategies over two-week period
- Evaluating how new strategies are working
- Tracking any concerns or barriers to using new strategies
- Planning to review the process of implementing and evaluating new strategies on message board in next 2 weeks

1 = The nurse addressed only one, two, or three of these topics:

- Trying strategies over two-week period
- Evaluating how new strategies are working
- Tracking any concerns or barriers to using new strategies
- Planning to review the process of implementing and evaluating new strategies on message board in next 2 weeks

0 = There was no statement about orienting the participant to the process of implementing and evaluating new strategies.

## **Exemplars:**

### Score 2:

- Nurse: “Now it's time to work on your plan. In two weeks we will come back to this. On May 13th I'll send you a follow-up message and ask you to think about how the plan has gone. Evaluation and reflection are critical parts of this process. Plans usually need adjustments and "tweaking". You'll want to ask yourself:
  - Were you able to use the strategies that you planned to try?
  - What worked and what didn't?
  - What worked best (can you use this approach in other ways?)
  - If it didn't work, why? Were there problems or concerns?

Do you need to adjust your goal as you either meet it or find you want to go a different direction?”

### Score 1:

- Nurse: “In 2 weeks I'll contact you again and ask how your strategies worked and if you are sleeping better. Meanwhile, please let me know if you have any more questions or thoughts about your itching.”

### Score 0:

- There was no instruction for the participant to the process of implementing and evaluating her strategies.

### **Subscale 7: Symptom follow up/Goal strategy review**

Goal: To evaluate the extent to which the interventionist discussed whether the participant was able to implement strategies, what problems were encountered, any concerns the participant had, how well strategies worked, and whether goal was reached.

**Item 24: Did the nurse assess whether the participant attempted to implement selected strategies?**

2 = The nurse asked whether the participant attempted to implement selected strategies.

1 = The nurse partially asked whether the participant attempted to implement selected strategies.

0 = The nurse did not ask whether the participant attempted to implement selected strategies.

**Exemplars:**

Score 2:

- Nurse: “I am curious to learn how things have gone. For each of the selected strategies, were you able to use them?”

Score 0:

- The nurse did not ask if the participant was able to implement the strategies.

**Notes:** The nurse could use the following standard post which covers target behavior for items 24, 25, and 26.

- I am curious to learn how things have gone. For each of the strategies, please tell me as much as you can in response to these questions?
  1. Were you able to use the above strategies?
  2. If not, what things prevented you from doing them?
  3. If yes, how well did these strategies work in helping you reach your goal of reducing your level of fatigue?
  4. Did you experience any problems or concerns as a result of any of these strategies?

**Item 25: Did the nurse assess barriers or concerns about use of selected strategies?**

2 = The nurse asked whether the participant had barriers or concerns in attempting to implement selected strategies.

1 = The nurse partially asked whether the participant had barriers or concerns in attempting to implement selected strategies

0 = The nurse did not ask whether the participant had barriers or concerns in attempting to implement selected strategies.

**Exemplars:**

Score 2:

- Nurse: “I am curious to hear how things have gone. For each of the selected strategies, were you able to use them? If not, what things prevented you from doing them? Did you experience any problems or concerns as a result of any of these strategies?”

Score 0:

- The nurse did not ask if the participant had barriers or concerns in attempting to implement selected strategies.

**Item 26: Did the nurse assess the effectiveness of the selected strategies?**

2 = The nurse asked whether the participant was successful in implementing the selected strategies.

1 = The nurse partially asked whether the participant was successful in implementing the selected strategies.

0 = The nurse did not ask whether the participant was successful in implementing the selected strategies.

**Exemplars:**

Score 2:

- Nurse: “I am curious to learn how things have gone. For each of the selected strategies, were you able to use them? I am curious to learn how things have gone. How well did these strategies work in helping you reach your goal of reducing your level of fatigue?”

Score 0:

- The nurse did not ask if the selected strategies were effective.

### **Subscale 8: goal and strategy revision**

Goal: To evaluate the extent to which the interventionist encouraged the participant to continue same pattern of implementing, evaluating, and modifying strategies to manage her symptom.



**Item 27: Did the nurse ask the participant whether she would like to modify her goals and strategies?**

2 = The nurse asked the participant whether she would like to modify her goals and strategies.

1 = The nurse partially asked the participant whether she would like to modify her goals and strategies.

0 = The nurse did not ask the participant whether she would like to modify her goals and strategies.

**Exemplars:**

Score 2:

- Nurse: “Please let me know how your fatigue strategies have been working for you when you can. I also want to know if you would like to make any changes in your plan.”

Score 0:

- The nurse did not ask if the participant wanted to make any changes about her symptom management plan.

**Item 28: a. If the participant was successful with previous strategies and does not want to make any changes, did the nurse affirm successes before skipping to #29?**

**b. If participant was successful with previous strategies, but wants to add additional strategies, did the nurse work with participant to identify potential new strategies?**

**c. If previous strategies were tried, but were not effective, did the nurse work with the participant to identify potential new strategies?**

**d. If previous strategies were not tried or not used consistently, did the nurse assist participant to identify ways to overcome any reported barriers to implementing strategies?**

2 = The nurse completely performed the expected behaviors such as using statements which demonstrate that the nurse appreciates at least part of what the participant has been doing.

1 = The nurse partially performed the expected behaviors.

0 = The nurse not performed the expected behaviors at all.

**Exemplars:**

Score 2:

- Nurse: “Wow, I’m so glad your plan for managing constipation and other bowel issues is helping you out. You did a nice job of managing the symptom.”

Score 1:

- The nurse never addressed this message posted by the participant:  
“The best thing is plain water-actually water with ice in a pretty glass – so I’m working on it. And little water after 8 pm so I don’t replace waking up from itching with waking up to go to the bathroom. I would say I’ve been successful at meeting this goal, but I’d like to reach a

point where I am drinking mostly just plain water” It appears that the itching was taken care of; but, there was something that the participant implied that she wanted to get a better plan.

Score 0:

- There was no statement made regarding the expected behaviors

**NOTE:** If the strategies are effective, the nurse is expected to compliment or praise participant efforts to manage symptoms. If the strategies are not effective/were not tried, the nurse is expected to:

- assess for and discuss any barriers that developed in implementation of strategies.
- work with participant to identify new/different strategies that she may be more able to integrate into her life.

**Item 29: Did the nurse emphasize the need for adjustments to plan over time to achieve good symptom management?**

2 = The nurse comprehensively emphasize the need for adjustments to plan overtime to achieve good symptom management by mentioning these two topics:

- A strategy may be needed an ongoing adjustment.
- A little of rationale as to why the adjustment is needed.

1 = The nurse only addressed that the plan may need adjustment.

0 = There was no statement about the need for adjustments to plan over time to achieve good symptom management.

**Exemplars:**

Score 2:

- Nurse: “Good symptom management plans often require trying out things and finding what works best for you. As you've already been talking about, you may require changes in medication or approaches. Remember, these plans are not a static thing. They will always need adjustments and modifications as you meet some goals, or find certain strategies just don't fit in your life. If something isn't working, let's see what else we can try or add to your plan. Many times a symptom requires many different approaches at the same time.”

Score 1:

- Nurse: “It is time to check in again and chat about how things have gone, as you tried some of the strategies. At this point, part of the process is to take some time to evaluate the plan and think about whether any changes or adjustments are needed.”

Score 0:

- There was no statement about the need for adjustments to plan over time to achieve good symptom management.

### **Subscale 9: teaching the RA process**

Goal: To evaluate the extent to which the interventionist identified and reiterated steps in RA process, began turning over RA process to participant when working on symptom 2, and encouraged independent use of RA process with symptom 3.

**Item 30: Did the nurse inform the participant regarding how the intervention will help her get better control of her symptom?**

(How the intervention works)

2 = The nurse completely informed the participant as to how the WRITE Symptoms intervention will help her get better control of her symptom by mentioning the intervention will lead her to these processes:

- Thinking about her symptom and how her symptom affects her life helps her understand her problem more clear
- Developing individualized goals and strategies to help her better manage her multiple symptoms.

1 = The nurse partially informed the participant as to how the WRITE Symptoms intervention will help her get better control of her symptom.

0 = There was no statement made regarding how the WRITE Symptoms intervention will help the participant get better control of her symptom.

**Exemplars:**

Score 2:

- Nurse: “Here is how it works. I will be asking many questions in the first few messages I write to you. This is for us to both get a full understanding of your experience with each symptom. As you think about the questions and write your responses, you may find you see some things more clearly or perhaps differently. This back-and-forth discussion works in two different ways. First, it leads you to make a specific plan for symptom management that you can fit well into your life and your needs. Second, it introduces you

to a way of thinking about symptom care for any future needs you may have. As you go through the steps in this problem-solving process, you can learn an approach to use with any symptom, not just the three we will focus on now.”

Score 1:

- Nurse: “Our discussion will help us to understand your experience with each symptom more clearly so that it may help us make a specific plan for your symptom management.”

Score 0:

- The nurse did not inform the participant regarding how the intervention would help her get better control of her symptom.



**Item 31: Did the nurse discuss a tentative agenda with the participant at the beginning of the session?**

2 = The nurse addressed all of these topics:

- The nurse and the participant will work together on each symptom at a time.
- The nurse and the participant will be communicating solely on the message board.
- The nurse works Monday through Friday and will be checking and replying the participant's messages within 24 hours on those days.

1 = The nurse addressed some of these topics:

- The nurse and the participant will work together on each symptom at a time.
- The nurse and the participant will be communicating solely on the message board.
- The nurse works Monday through Friday and will be checking and replying the participant's messages within 24 hours on those days.

0 = The nurse did not discuss a tentative agenda with the participant at all.

**Exemplars:**

Score 2:

- Nurse: "I will be in regular communication with you throughout this symptom management program. We will work on each symptom at a time. We will be communicating solely on the message board. I work Monday through Friday and will be checking for any messages from you on those days. I will also try to reply your post within 24 hours on those days. Other members of the research team will be in touch with you at various times by phone or email. The research office is open Monday through Friday during regular business hours."

Score 1:

- Nurse: “I will be in regular communication with you throughout this symptom management program. We will work on each symptom at a time. We will be communicating solely on the message board.”

Score 0:

- There was no statement made regarding a tentative agenda of the intervention.

**Item 32: Did the nurse teach the participant the process of the representational approach during the 2<sup>nd</sup> and/or 3<sup>rd</sup> symptom?**

2 = The nurse addressed all aspects of the RA process during 2<sup>nd</sup> and/or 3<sup>rd</sup> symptom

1 = The nurse addressed some aspects of the RA process during 2<sup>nd</sup> and/or 3<sup>rd</sup> symptom

0 = The nurse addressed no aspects of the RA process during 2<sup>nd</sup> and/or 3<sup>rd</sup> symptom

**Exemplars:**

Score 2:

- Nurse: “Remember the types of questions we asked about your abdominal bloating?  
We'll be starting there; but this time, I'm going to let you take more of a lead. Think of this as your chance to learn more about the whole process that we are using to assess and better manage these symptoms. It was really helpful for me when we were working on bloating and you described your typical day. In your messages, you talked about the ways that abdominal bloating affects your life and the way you function. You were also thinking and writing about how you could make changes to get better control. We love those details! They're a key part of this process. Now we're going to use the same process for the next target symptom. The first part of the process is for you to look at your next symptom (whatever you want to work on next) and its impact on your life. You'll want to think and write about these questions:
  - What does your fatigue or pain (pick one) feel like and how severe is it?
  - What do you think is causing your symptom?
  - When did you first notice it and does it follow any sort of pattern?
  - How has this symptom affected your life? Are you unable to do anything because of it?

- What are you doing or have you tried in the past to manage/control your fatigue or pain?
- Does that work and do you have any concerns about what you are doing to manage/control it?
- How does it your fatigue or pain affect you emotionally?"

Score 1:

- Nurse: "With this conversation on the message board, we'll start to work on your next symptom of fatigue. But this time, I'm going to let you take more of a lead. It was very helpful for me when we were working on constipation and you described your typical day. In your messages, you talked about the ways that constipation affects your quality of life and the way you function. Now we're going to use the same process for the next target symptom."

Score 0:

- The nurse did not teach or turn over the representational approach to the participant when working on the 2<sup>nd</sup> and/or the 3<sup>rd</sup> symptom.

**Item 33: Did the nurse encourage the continued use of the representational approach in the future?**

2 = The nurse comprehensively encouraged the use of the representational approach in the future by encouraging the participant to manage any further symptoms by:

- Writing about how her symptoms are affecting her life.
- Thinking about her goals for better symptom management.
- Reading through the Symptom Care Guide for her bothersome symptoms.
- Writing down the strategies she would like to try or the questions that she has for her doctor or her health care team.
- Making time during her appointments to discuss what she has written down.
- Evaluating her symptom care plan to decide whether it is helping her.
- Giving feedback to doctor or her health care team.
- Encouraging her doctor or her health care team to help her find different or better approaches in order to get the best control possible.

1 = The nurse partially encouraged the participant use the representational approach.

0 = The nurse did not encourage the use of the representational approach in the future.

Note: The nurse could also encourage the continued use of the representational approach in the future by posting two standardized posts which covered all required behaviors for this item.

**Exemplars:**

Score 2:

- Nurse: “It is our hope that you continue to use this process whenever you are experiencing symptoms that interfere with your life. Every now and then:

- Sit down and write about how your symptoms are affecting you.
- Think about your goals for better symptom management.
- Read through the Symptom Care Guide for your bothersome symptoms.
- Write down the strategies that you would like to try or the questions that you have for your doctor.
- Make time during your appointments to discuss what you have written down.
- Evaluate your symptom care plan to decide whether it's helping you.
- Give feedback to your doctors.
- Encourage them to help you find different or better approaches in order get the best control possible.”

Score 1:

- Nurse: “Probably a good way for you to think about this is as good practice for using this process on a symptom you know very well. Our hope is that this is a process you'll be able to use manage symptoms and new situations in the future, so that you can feel your best.”

Score 0:

- There was no statement about encouraging the use of the representational approach in the future.

**Behaviors essential to the WRITE Symptoms intervention but not unique to them (2 subscales)**

**Subscale 10: consistent/flexible application of protocol**

Goal: To evaluate the extent to which the interventionist demonstrated consistent, but flexible application of protocol such as being able to modify sequence and focus of the intervention while still completing the full RA for at least 1 symptom.

**Item 34: Did the nurse demonstrate individualization in the protocol based on participant's responses?**

2 = The nurse never used same standardized posts more than one time without modifying.

1 = The nurse used a standardized post without modifying the post twice.

0 = The nurse used standardized posts without modifying at least twice.

**Exemplars:**

Score 2:

- The nurse never used same standardized posts more than one time without modifying.

Score 1:

- The nurse used this standardized post without modifying the post twice "I want to take a moment to reflect on what we just accomplished here..."

Score 0:

- The nurse used this standardized post without modifying the post three times "I want to take a moment to reflect on what we just accomplished here..."



**Item 35: Was the nurse flexible in addressing the participant's questions/ problems as they arose?**

2 = The nurse addressed (if not completely addressed, at least responded to) every question/ problem brought up by the participant.

1 = In general, the nurse responded to the participant's questions/ problems as they arose; but, The nurse did not respond to the participant's questions/ problems as they arose one time.

0 = In general, the nurse responded to the participant's questions/ problems as they arose; but, the nurse did not respond to the participant's questions/ problems as they arose at least twice.

**Exemplars:**

Score 2:

- The nurse never ignored the participant's questions/ problems as they arose by persisting only with the current working topic.

Score 1:

- When working on pain management, the participant complained that she had constipation but the nurse never responded to the constipation.

Score 0:

- When working on pain management, the participant posted three separate messages that she had constipation but the nurse never responded to her posts about the constipation.

**Item 36: Did the nurse break down complex information or experiences into manageable pieces?**

2 = In general, the nurse could break down complex information or experiences into manageable pieces.

1 = The nurse could partially break down complex information or experiences into manageable pieces.

0 = The nurse did not break down complex information or experiences into manageable pieces at all.

**Exemplars:**

Score 2:

- Thank you for giving more information about your fatigue and how it affects your life. Really helps me get a fuller picture. Glad you are noticing less fatigue since you've been off chemo this past month. I can also see how the symptoms of diabetes could very much complicate this for you even more. Passing out at the grocery store sounds pretty scary. Also, I can see how arthritis pain could interfere with getting a good night's sleep, which in turn impacts your daytime sleepiness and levels of fatigue. You mentioned you were thinking about taking Aleve or something similar. Have you tried that? Does your HCT have recommendations for managing your arthritis pain?

Score 0:

- There was no statement that the nurse helped the participant broke down complex information or experiences into manageable pieces.

**Item 37: Did the nurse use probes appropriately?**

(Probe when more information is needed, not probe when detail is provided spontaneously)

2 = The nurse always probed with additional questions when more information was needed; and, the nurse never probed when detail is already provided.

1 = In general, the nurse probed with additional questions when more information was needed; and, the nurse never probed when detail is already provided. However, there was one time the nurse either missed probing when more information was needed or probed when detail was already provided.

0 = In general, the nurse probed with additional questions when more information was needed; and, the nurse never probed when detail is already provided. However, there were at least two times when the nurse either missed probing when more information was needed or probed when detail was already provided.

**Exemplars:**

Score 2:

- Participant: "I have had a hard time getting in fluids"
- Nurse: "It does seem like you're having a hard time getting in fluids (especially in the afternoon and on), but can you tell me if you're able to eat? Can you share a little about what you eat?"

Score 0:

- Participant: "I have had a hard time getting in fluids"

The nurse did not ask any question regarding the participant's post.

**Item 38: Did the nurse use language regarding cooperation and working together?**

2 = The nurse always communicated with the participant in a collaborative manner by taking participant's perception into account when working/planning on any tasks. The nurse always used expression of mutual respect.

1 = The nurse partially communicated with the participant in a collaborative manner.

0 = The nurse did not communicate with the participant in a collaborative manner at all.

**Exemplars:**

Score 2:

- Nurse: "I'll be here for you to "talk" it out as we work through this part of the process. Then we can move on to coming up with a plan to help you manage your hot flashes better. You did a great job of describing your fatigue, especially the many things you have been doing or plan to do. I can tell you are already doing a lot of thinking and problem-solving. With this process we will continue to do more of that. I really appreciate your sharing these feelings and thoughts with me."

Score 0:

- The nurse did not acknowledge the participant's recent comments about hot flashes and fatigue. The nurse made no mention of the plan, and did not reach out to the participant to work on it together: "It's clear to me you've been thinking about things a lot recently. Is there anything that's been bothering you recently that you want to tell me about?" (Occurred on two separate occasions).

### **Subscale 11: therapeutic alliance**

Goal: To evaluate the extent to which the interventionist developed therapeutic alliance in addressing goals of better symptom management such as avoiding use of judgmental statements, and willingness to address emotional or difficult topics.

**Item 39: Did the nurse *avoid* emotional/difficult topics introduced by the participant?**

(Reverse Score)

2 = The nurse always addressed every emotional/difficult topic introduced by the participant. The nurse expressed acceptance and understanding of the participant's feelings by using statements which demonstrated that the nurse was "listening" to the participant, and then responded with a statement that reflected the essence of what the nurse thought regarding those topics. The nurse used a statement that she/he cares about what the participant was telling.

1 = The nurse partially addressed emotional/difficult topic introduced by the participant.

0 = The nurse never addressed an emotional/difficult topic introduced by the participant.

**Exemplars:**

Score 2:

- The participant "...returned home from a wedding on Sunday and Monday my brother died from rectal cancer and other ailments. It is difficult for me to get all of my homework done because of all my problems with my health and family matters. The nurse addressed the participant's post by posting this: "It sure sounds like you've had an awful lot going on these past 2 weeks, though... Even a fun event like a wedding can be tiring, especially when you have other things going on. .. I'm so sorry to hear about your brother."

Score 0:

- The participant brought up the death of a family member two times.

The nurse did not acknowledge the two posts.

**Item 40: Did the nurse present alternative views or opinions in a non-judgmental manner?**

2 = The nurse always expressed acceptance the participant's perspectives neutrally. The nurse always communicated with the participant without judging or evaluating in any way. If there was a contrary issue, the nurse did not directly oppose the participant's perspective. Rather, if appropriate, the nurse invited the participant to consider new information and offered new perspectives. The nurse responded to the participant's perspectives without defensiveness (i.e. arguing, interrupting).

1 = The nurse partially presented alternative views or opinions in a non-judgmental manner.

0 = The nurse did not present alternative views or opinions in a non-judgmental manner at all.

**Exemplars:**

Score 2:

- Nurse: "I realize that you are keeping up with your Natural Healing e-zine readings. Many of them are very interesting and seem worth trying especially the nutritional strategies, which are quite affordable. However, make sure you keep your HCT informed of anything new that you are trying. Believe it or not, they are truly interested in new approaches, too."

Score 0:

- There was one time the nurse posted one message as follows. Nurse: "A lot of the new natural healing methods published nowadays are misleading. Many of them are written by non-medical people and often even people without any nutritional training. I don't buy into any of it."

**Item 41: In general, did the nurse ask questions which were open-ended?**

2 = In general, the nurse asked open-ended questions and let the participant “talk”. The nurse used questions, which encouraged the participant to take control of the direction of the reply, which helps the participant provide more information and expresses concern.

1 = The nurse rarely asked open-ended questions and did not let the participant “talk”.

0 = The nurse never asked an open-ended question.

**Exemplars:**

Score 2:

- Nurse: “Sometimes it is hard to talk with your spouse regarding concerns about sex. Can you tell me how you and your husband are doing in this area of your lives together?”

Score 0:

- In one long post, the nurse asked only close-ended questions:

Sex is sometimes the hardest thing to deal with for couples grappling with cancer. Do you agree?

Is it more frustrating for you than your husband?

Did you have a good sex life before the cancer hit?

Have you thought about counseling?

Would your husband be open to that?”



**Item 42: Did the nurse invite the participant to ask questions?**

2= The nurse invited the participant to ask questions at least two times. One time must occur in the first 3 posts; or, the participant spontaneously asks frequent questions.

1 = The nurse gave only one invitation OR the nurse gave multiple invitations; but none of them occurred within first 3 posts.

0 = The nurse did not invite the participant to ask questions at all.

**Exemplars:**

Score 2:

- The nurse posted these two messages:
  - Second post: “Let me know if you have any questions.”
  - Fourth post: “If you have any questions or concerns, please don’t hesitate to let me know I’m here to answer any questions you may have.”

Score 1:

- The nurse posted this message after post number 3 “Please let me know if you have any questions.”

Score 0:

- The nurse never invited the participant to ask questions.

**Item 43: Did the nurse periodically check that her understanding/ interpretation of the participant's experience was accurate?**

2 = The nurse checked that her understanding / interpretation of the participant's experience was accurate at least twice.

1 = The nurse checked that her understanding / interpretation of the participant's experience was accurate only one time.

0 = The nurse did not check that her understanding / interpretation of the participant's experience was accurate.

Note: This item is about validation of the participant's experience or symptoms. It is not used to assess whether the nurse validated if a goal / strategy is acceptable to the participant (which is different from item number 21). If the nurse summarizes but does not validate that she has made accurate interpretations / summaries, then the score would be 0.

**Exemplars:**

Score 2:

- The nurse posted two messages in two different posts
  - Third post: "You mentioned in your last post about "what causes the constipation and what you should do". I'm not sure if my understanding is correct that you think your constipation is a result of your pain medication. You also talked about how the hot water from your spa tub enhances your nausea "if I'm having nausea before then I don't go in the tub." What do you think is the cause of this nausea?"
  - Seventh post: "In previous posts you discussed the feelings of drowsiness and foginess and you do not want to take a stronger pain medication because of the

anticipated side effects. Your description of your pain is really significant. Could you tell me a bit about the pain associated with your peripheral neuropathy? Do you mean that they occurred at the same time?"

Score 1:

- The nurse posted one message asking the participant about this "Do you think it's the side effects (woozy, constipation) or safety that are your major concern?"

Score 0:

- The nurse never posted a message to validate if her understanding / interpretation of the participant's experience was accurate.

**Item 44: Did the nurse end each phase by summarizing the main points covered?**

2 = The nurse posted statements to demonstrate that she ended each phase by summarizing the main points covered at least twice.

1 = The nurse posted statements to demonstrate that she ended each phase by summarizing the main points covered one time.

0 = The nurse never posted statements to demonstrate that she ended each phase by summarizing the main points covered.

**Exemplars:**

Score 2:

- Posts similar to the following occurred at least twice: “I can see you have accomplished a lot about pain management over the last few days. As you make your adjustments and figure out the balance between side effects and the pain, keep your goal for an acceptable pain level in mind. I was wondering if you might like to adjust your goal for pain level. You have below 5 now. It's good to have high expectations for pain management. So, here's today's "homework":  
  
1. I'll make adjustments in your plan. Let me know how that looks and you can now continue to work on pain for the next 2 weeks. I'll ask you about it again on April 12. Remember, I will ask you questions about how your plan worked, what was good, what changes you'd like to make, and so on. Evaluation is also a very important part of this process.”

2. “Also, please read my follow-up message for you under the Abdominal Bloating Conversation. Can you answer these questions for me? Sounds like you were able to chat with Judy (the nurse) about it. Do we need to make any adjustments in this plan? After I hear back from you on these 2 things we will move on to your final and third symptom, fatigue, but I'll let you get through today's homework first.”

Score 1:

- Posts similar to what scored 2 (above) occurred once.

Score 0:

- There was no statement demonstrate that she ended each phase by summarizing the main points covered.

**Proscribed behaviors in the WRITE Symptoms intervention (1 subscale)**

**Subscale 12: Fidelity to scope of intervention**

Goal: To evaluate the extent to which the interventionist focused on symptom management, and avoided prescriptive advice and recommendations that are not supported by evidence-based Symptom Care Guides.

**Item 45: Did the nurse *avoid* giving advice on cancer or cancer treatment?**

2 = The nurse did not make specific treatment recommendations at all, but provided general suggestions about symptom management and encouraged the participant to talk with her HCT about the specific treatment recommendations.

1 = N/A

Note: The nurse gave specific advice on cancer or cancer treatment is a major violation. Therefore, if the nurse did, this item would be scored 0.

0 = The nurse gave specific advice on cancer or cancer treatment.

**Exemplars:**

Score 2:

- Nurse: “You had a lot of questions for me that I cannot answer specifically because I am not there as part of your HCT. In addition to helping you make a plan with strategies for managing your symptoms, one of the things I **can** help you with during this program is to come up with ways to talk with your team more effectively.”

Score 0:

- Nurse: “Complementary and alternative medicine (CAM) have obtained more attention in cancer treatment. There have been a lot of claims made by CAM treatment providers about CAM’s advantages that sound promising. I’d like to suggest you thinking about this as one of your treatment options.”

**Item 46: Did the nurse *avoid giving prescriptive* advice on medical/pharmacologic interventions?**

2 = The nurse did not make specific medication or dosage recommendations at all; rather, she encouraged the participant to talk with her HCT about the medication or dosage recommendations.

OR

2 = The nurse provided general suggestions about medical/pharmacologic interventions *included in SCGs* **and** encouraged the participant to discuss with her HCT in more detail about the medication or dosage recommendations.

1 = The nurse provided general suggestions about medical/pharmacologic interventions *included in SCGs*; but, she did not tell the participant talking with her HCT.

0 = The recommended medical/pharmacologic interventions **not** *included in SCGs*.

**Exemplars:**

Score 2:

- Nurse: “So, those nasty foot pains are back again? That can be so annoying especially at night when you’re trying to get to sleep. However, I’m here to help you through the symptom discussion and management, but I recommend you contact your HCT to discuss what might be prescribed to effectively get the pain calmed down and get you a good night’s rest.”



Score 1:

- Nurse: “So, those nasty foot pains are back again? That can be so annoying especially at night when you’re trying to get to sleep. You might consider going to the pharmacy and pick up some Ibuprofen, like Advil, to get the pain calmed down so you can get some sleep.” This is Score 1 because the recommended OTC solution is in the SCG; however, the nurse did not recommend that the patient confer with her HCT about the foot pain.

Score 0:

- Nurse: “Special diets or supplements such as coenzyme Q 10 and antioxidants sometimes are used in the treatment of people with cancer. I’d recommend you try taking the coenzyme Q10 and antioxidants every day.”

**Item 47: Did the nurse *avoid* recommending strategies not included in algorithms/ SCGs?**

2= The nurse never recommended strategies not included in algorithms/ SCGs.

1 = N/A

Note: The nurse recommended strategies not included in algorithms/ SCGs is a prohibited behavior. Therefore, if the nurse did, this item would be scored 0.

0 = The nurse recommended strategies not included in algorithms / SCGs.

**Exemplars:**

Score 2:

- There was no statement that the nurse recommend strategies not included in algorithms/ SCGs

Score 1:

- N/A

Score 0:

- The participant has constipation; but, the nurse encouraged increasing the consumption of liquids within the day by suggesting the following strategies:

For your morning coffee, make your coffee with 2 cups of water. Consume this by 1pm.

**Item 48: Did the nurse ask appropriate safety questions based on symptom algorithm?**

2 = The nurse comprehensively asked safety questions based on a symptom algorithm.

1 = The nurse partially assessed safety issues related to the symptom based on a symptom algorithm.

0 = The nurse never asked safety questions based on a symptom algorithm.

N/A = there are no safety questions included in the algorithm for this symptom (e.g. hair loss)

**Exemplars:**

Score 2:

- Nurse: “You did a great job of going through my list of questions.  
I feel like I am getting a pretty full picture of your neuropathy and how it affects your life. It sounds like you have made many adjustments on your own. I do have a few more questions.
  - Do you feel safe doing routine activities such as driving and walking?
  - Can you feel the pedals in the car (or 4-wheeler), feel balanced when you walk?”

Score 1:

- N/A

Score 0:

- The nurse never asked appropriate safety questions based on symptom algorithm. For example; for constipation, the nurse never assessed if the participant had more than 3 days of no bowel movement, vomiting, and / or abdominal pain.

**Item 49: Did the nurse tell the participant to contact her HCT if any new symptoms arise or if symptom worsens?**

2 = The nurse suggested the participant contact her HCT, even if the participant did not bring up changes or new problems.

1 = The nurse suggested the participant contact her HCT in another context or in general, but did not suggest contacting the HCT in case anything new comes up or if symptoms become worse.

0 = If the participant mentioned changes in her status (implicit or explicit), and the nurse did not recommend the participant contact her HCT.

OR

0= The nurse never suggested the participant contact her HCT even for symptoms the participant and the nurse were communicating about.

**Exemplars:**

Score 2:

- Nurse: “Just a word of caution... sometimes it can take awhile to get in to see a dermatologist. If your skin rash gets worst, you need to consider enlisting the help of your regular doctor to get in sooner.”

Score 1:

- Nurse: “I want to suggest that you discuss your symptom with your HCT in the next visit.”

Score 0:

- The nurse never suggested the participant contact her HCT.

**Behaviors necessary for asynchronous web-based interventions (1 subscale)**

**Subscale 13: Asynchronous web-based skills**

Goal: To evaluate the extent to which the interventionist used effective web-based intervention behaviors such as: responding within 24 hours, using strategies to make text more reader friendly, matching tone, reading level, and number of questions/text appropriate to information provided by participant.

**Item 50: Did the nurse respond to the participant's posts within 24 hours 5 days/week?**

2 = The nurse responded to every participant's post within 24 hours, Mondays through Fridays (except for weekend and holidays), after the participant posted her message.

1 = The nurse responded to some of the participant's posts within 24 hours, Mondays through Fridays (except for weekend and holidays), after the participant posted her message; but, she did not respond to the participant's posts on time once.

2 = The nurse did not respond to the participant's posts within 24 hours, Mondays through Fridays, at least two times.

**Exemplars:**

Score 2:

- The participant posted her message on 01/04/2011 at 08:30:06

The nurse replied on 01/05/2011 at 08:30:06

Score 1:

- There were some posts replied to on time (similar to that was scored 2 [above]); but, there was one post replied to late (similar to that was scored 0 [below]).

Score 0:

- There were at least two times when responses from the nurse were late (similar to below example).

The participant posted her message on 01/04/2011 at 08:30:06

The nurse replied on 01/06/2011 at 06:30:05



**Item 51: Did the nurse use strategies to make text more reader-friendly?**

(E.g. use of white space, numbering/bullets, organization of messages by symptom, use of descriptive subject lines)

2 = The nurse always made every post a reader-friendly.

1 = There was one post that was not reader-friendly.

0 = There were at least two posts that were not reader-friendly.

**Exemplars:**

Score 2:

- Nurse: "I have listed below what I think you said about your goal and strategies.

**Goal:** "My goal is to maintain my current weight of 132 pounds and not gain any more while on treatment; while also managing side effects of chemo (Nausea/vomiting)."

**Strategies**

I will:

1. Continue current diet and nutrition strategies
2. Plan meals in advance
3. Limit junk food to one small "treat" per day at the most
4. Eat only when hungry
5. Focus on eating plenty of vegetables and fruits (**how many?**)
6. Concentrate on portion size; eat only one serving size, even while at restaurants when larger portions served

Please let me know if this looks accurate to you."

Score 1:

- There were some posts similar to that was scored 2 (above); but there was one post similar to what was scored 0 (below)

Score 0:

- Nurse: “I don't want to overwhelm you with questions...so if this is too much for you to put into a message back to me at one time ...that is fine! So, here are the questions:  
Do you ever get so anxious that you feel you might hurt yourself or someone else?  
Before being diagnosed with cancer, did you have difficulties with anxiety? Aside from talking to your counselor (and I am really glad that has helped you!), is there anyone in your circle of friends and family that you can talk to about your anxiety?  
Can you tell me anything more about how this symptom affects you? Can you describe some of the ways that you managed this before...What has helped? What didn't help? Have you discussed your anxiety with your doctor and health care team (HCT)? ”

**Item 52: Did the nurse offer to break up information into smaller posts?**

2 = The nurse offered to write shorter posts if the participant preferred and also welcomed the participant to break her responses into more than one post

1 = The nurse encouraged the participant to either break up her responses in multiples posts, or, to ask the nurse to make shorter posts.

0 = The nurse never made a statement to offer breaking up information into smaller posts.

**Exemplars:**

Score 2:

- Nurse: “I asked you quite a few questions today. If you want to break up your responses into a couple of posts, that's fine. Also, let me know if you want messages to you to be shorter.”

Score 1:

- Nurse: “Please feel free to answer however you like and break the questions up so that they make sense to you.”

Score 0:

- There was no statement demonstrating the nurse offered breaking up information into smaller posts.

**Item 53: In general, were the numbers of questions asked by the nurse in each post appropriate to the number of issues raised in the participant's post?**

2 = The number of questions asked by the nurse in each post always reflected the number of issues raised in the participant's post and, when appropriate, raised other related important issues.

1 = There was a post in which the number of questions asked by the nurse were not appropriate to the number of issues raised by the participant.

0 = There were at least two posts in which the questions asked by the nurse in each post were not appropriate to the number of issues raised by the participant.

**Exemplars:**

Score 2:

- Participant: Hi, it's been a pretty tough day for me. When I got up I had a raging headache. I got enough sleep. Is there a chance I'm sleeping too much? I've been eating pretty well.

Nurse: Hi, good to hear from you. I'm sorry to learn you awakened with a headache today. Is the headache still going on? Is there anything else going on along with the headache? For example, is your vision clear or blurry? Is the headache located in one particular area of your head? I was also wondering if you've ever had migraines or seasonal allergies. Can you give me some details? Regarding your wondering if you're sleeping too much and whether that could cause a headache, the answer may be related to how long you're sleeping and things such as food intake being disrupted. I want to suggest that you ask this question of your healthcare provider.

Score 1:

- Participant: Hi, it's been a pretty tough day for me. When I got up I had a raging headache. I got enough sleep. Is there a chance I'm sleeping too much? I've been eating pretty well. I've also been constipated for the past two days.

Nurse: Hi, good to hear from you. I'm sorry to learn you wakened with a headache today. Is the headache still going on? Is there anything else going on along with the headache? For example, is your vision clear or blurry? Can you give me some details? Regarding your wondering if you're sleeping too much and whether that could cause a headache, I want to suggest that you ask this question of your healthcare provider.

(Note: Because the nurse, in this one post, did not acknowledge the constipation issue raised by the participant, the score is 1.)

Score 0:

- Participant: Hi, it's been a pretty tough day for me. When I got up I had a raging headache. I got enough sleep. Is there a chance I'm sleeping too much? I've been eating pretty well. Around lunchtime, I had a nosebleed that lasted about a half hour.

Nurse: Hi, good to hear from you. I'm sorry to learn you wakened with a headache today. Can you give me some details?

Participant: The headache is mostly in the front of my head like I have a blanket on my forehead. I did take some aspirin but it didn't make the pain go away. I'm worried about the nosebleed. Why would that happen?

Nurse: Have you ever experienced migraine headaches or do you have a history of allergies?

(Note: Because the nurse, in two posts, did not acknowledge the constipation (in one post) and the nosebleed (noted in a second post) the score is 0.

**Item 54: Did the nurse match tone, reading level, use of humor to that of the participant?**

2 = The nurse always matched tone, reading level, and use of humor to that of the participant.

1 = One posted message did not match tone, reading level, and use of humor to that of the participant.

0 = There were at least two times the nurse posted her message that did not match tone, reading level, use of humor to that of the participant.

**Exemplars:**

Score 2:

- Participant: This is incredible! I never thought I would feel this sick and throw up so much. I feel like no one told me this was going to be this horrible. I am taking compazine like it's a daily vitamin.

Nurse: Sounds like it's been rough going for you recently. When did this start? Just today or last night? It seems like a long time ago; but, remember before chemo started, this was included as a possible side effect. I know it doesn't make you feel any better, but at least you know it's not unusual. I'm glad you're using the compazine. Are you getting fast relief from it? How much are you taking? Hey, since you brought up vitamins...are you taking any? ;--)

Score 1:

- Participant: This is incredible! I never thought I would feel this sick and throw up so much. I feel like no one told me this was going to be this horrible. I am taking compazine like it's a daily vitamin.

Nurse: Wow, sorry to learn this. I'm sure when side effects of chemo were explained to you nausea and vomiting were included. So, you are now taking compazine every day?

Score 0:

- Participant: This is incredible! I never thought I would feel this sick and throw up so much. I feel like no one told me this was going to be this horrible. I am taking compazine like it's a daily vitamin.

Nurse: I'm sure that when the side effects of chemo were first explained to you that nausea and vomiting were included. So, you are now taking compazine every day?

Participant: Yes, I wrote that. Grrr. I'm puking my guts out, I'm uncomfortable and I feel like no one warned me it would be this bad.

Nurse: Okay, I understand you're taking the compazine daily. Is it just one time a day or multiple times a day?



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